UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

IN RE: NEW ENGLAND COMPOUNDING PHARMACY, INC. PRODUCTS LIABILITY LITIGATION	MDL No. 2419
THIS DOCUMENT RELATES TO:	Dkt. No. 1:13-md-2419 (RWZ)
Suits Naming Saint Thomas Outpatient Neurosurgical Center, LLC And Related Defendants	

PLAINTIFFS' STEERING COMMITTEE'S RESPONSES TO SAINT THOMAS OUTPATIENT NEUROSURGICAL CENTER, LLC, HOWELL ALLEN CLINIC, A PROFESSIONAL CORPORATION, JOHN W. CULCLASURE, MD, AND DEBRA V. SCHAMBERG, RN CNOR'S, FIRST REQUESTS FOR ADMISSIONS PROPOUNDED TO THE PLAINTIFFS

Pursuant to Rules 26 and 36 of the Federal Rules of Civil Procedure, the Plaintiffs' Counsel hereby responds to the First Interrogatories and Requests for Admission Propounded by the Defendants, Saint Thomas Outpatient Neurosurgical Center, LLC ("Saint Thomas Clinic"), Howell Allen Clinic, John W. Culclasure, MD, and Debra V. Schamberg, RN (collectively "Defendants" or "Saint Thomas Clinic Defendants").

INSTRUCTIONS DEFINITIONS AND OBJECTIONS

1. The term "Plaintiffs" shall mean all Plaintiffs who have pending cases against any of the Saint Thomas Clinic Defendants in active cases in the MDL.

2. The term "Plaintiffs' Counsel" shall mean the Tennessee State Chair as designated by Plaintiffs' Steering Committee pursuant to MDL Order No. 2.

3. The term "MDL" shall mean the multidistrict litigation *In re New England Compounding Pharmacy, Inc. Products Liability Litigation*, MDL 2419, currently pending before Judge Rya Zobel in the United States District Court for the District of Massachusetts.

4. The following responses are meant only to apply to cases pending in the MDL against the Saint Thomas Clinic Defendants and are not intended to be nor should they be considered to bind or apply in any other case pending in the MDL.

5. Many of the RFAs submitted call for the admission or denial of facts that are not reasonably calculated to lead to the discovery of admissible evidence, by admitting any RFA below, Plaintiffs do not concede that any response is admissible at trial in this matter.

RESPONSES TO REQUESTS FOR ADMISSIONS

REQUEST FOR ADMISSION NO. 1:

The Health Care Procedure Coding System ("HCPCS") code, J1040, existed in 2012 for billing third-party payors and/or patients separately for the steroid administered during epidural steroid injections.

RESPONSE TO REQUEST FOR ADMISSION NO. 1:

Admitted that HSPCS code J1040 existed in 2012 for billing purposes and for providing additional detail about a procedure. Denied to the extent that the RFA implies that the use of such code would indicate and/or lead to a separate payment for the steroid administered during epidural steroid injections.

REQUEST FOR ADMISSION NO. 2:

No other HCPCS code existed to bill third-party payors and/or patients separately for the steroid administered during epidural steroid injections.

RESPONSE TO REQUEST FOR ADMISSION NO. 2:

Denied.

REQUEST FOR ADMISSION NO. 3:

These Defendants did not bill any Plaintiff-patients, or their third-party payors, for the methylprednisolone acetate ("MPA") from the New England Compounding Pharmacy, Inc. d/b/a New England Compounding Center ("NECC") using the J1040 code.

RESPONSE TO REQUEST FOR ADMISSION NO. 3:

Plaintiffs are without sufficient evidence to admit or deny this statement at this time. Discovery has only recently begun and fulsome discovery has not yet taken place. Moreover, to the extent all relevant documents have not yet been produced, this knowledge is in the possession of defendants at this time.

REQUEST FOR ADMISSION NO. 4:

NECC and its owners, managers, employees, and agents owed a duty to the Plaintiffs to comply with the recognized standard of acceptable professional practice for compounding or manufacturing MPA and/or to exercise reasonable care when compounding or manufacturing the MPA at issue.

RESPONSE TO REQUEST FOR ADMISSION NO. 4:

. Plaintiffs object to the extent that this RFA requires Plaintiffs to admit to a legal conclusion which is not a permissible use of Rule 36 RFAs. *See e.g.*, *Iantosca v. Benistar Admin Servs., Inc.*, Case No. 08-11785, 2012 U.S. Dist. LEXIS 7896 (D. Mass. 2012); *In re Tobkin*, 578 Fed. Appx. 962 (11th Cir. 2014).

REQUEST FOR ADMISSION NO. 5:

NECC and its owners, managers, employees, and agents breached their duty to the Plaintiffs.

RESPONSE TO REQUEST FOR ADMISSION NO. 5:

Plaintiffs object to the extent that this RFA requires Plaintiffs to admit to a legal conclusion which is not a permissible use of Rule 36 RFAs. *See e.g.*, *Iantosca v. Benistar Admin Servs., Inc.*, Case No. 08-11785, 2012 U.S. Dist. LEXIS 7896 (D. Mass. 2012); *In re Tobkin*, 578 Fed. Appx. 962 (11th Cir. 2014).

REQUEST FOR ADMISSION NO. 6:

The breach of duty the owed by NECC and its owners, managers, employees and agents to the Plaintiffs was a proximate cause of the Plaintiffs' alleged injuries and damages.

RESPONSE TO REQUEST FOR ADMISSION NO. 6:

Plaintiffs object to the extent that this RFA requires Plaintiffs to admit to a legal conclusion which is not a permissible use of Rule 36 RFAs. *See e.g.*, *Iantosca v. Benistar Admin Servs., Inc.*, Case No. 08-11785, 2012 U.S. Dist. LEXIS 7896 (D. Mass. 2012); *In re Tobkin*, 578 Fed. Appx. 962 (11th Cir. 2014).

REQUEST FOR ADMISSION NO. 7:

Medical Sales Management, Inc. and/or Medical Sales Management SW, Inc. and their owners, managers, employees, and agents owed a duty to the Plaintiffs to exercise reasonable care when marketing and selling NECC's products, including MPA.

RESPONSE TO REQUEST FOR ADMISSION NO. 7:

Plaintiffs object to the extent that this RFA requires Plaintiffs to admit to a legal conclusion which is not a permissible use of Rule 36 RFAs. *See e.g., Iantosca v. Benistar Admin Servs., Inc.*, Case No. 08-11785, 2012 U.S. Dist. LEXIS 7896 (D. Mass. 2012); *In re Tobkin*, 578 Fed. Appx. 962 (11th Cir. 2014).

REQUEST FOR ADMISSION NO. 8:

Medical Sales Management, Inc. and/or Medical Sales Management SW, Inc., and their owners, managers, employees, and agents, breached their duty to the Plaintiffs when marketing and selling NECC's products.

RESPONSE TO REQUEST FOR ADMISSION NO. 8:

Plaintiffs object to the extent that this RFA requires Plaintiffs to admit to a legal conclusion which is not a permissible use of Rule 36 RFAs. *See e.g., Iantosca v. Benistar Admin Servs., Inc.*, Case No. 08-11785, 2012 U.S. Dist. LEXIS 7896 (D. Mass. 2012); *In re Tobkin*, 578 Fed. Appx. 962 (11th Cir. 2014).

REQUEST FOR ADMISSION NO. 9:

Medical Sales Management, Inc. and/or Medical Sales Management SW, Inc. and their owners, managers, employees, and agents' breach of their duty to the Plaintiffs was a proximate cause of the Plaintiffs' alleged injuries and damages.

RESPONSE TO REQUEST FOR ADMISSION NO. 9:

Plaintiffs object to the extent that this RFA requires Plaintiffs to admit to a legal conclusion which is not a permissible use of Rule 36 RFAs. *See e.g., Iantosca v. Benistar Admin*

Servs., Inc., Case No. 08-11785, 2012 U.S. Dist. LEXIS 7896 (D. Mass. 2012); *In re Tobkin*, 578 Fed. Appx. 962 (11th Cir. 2014).

REQUEST FOR ADMISSION NO. 10:

When constructing the cleanroom(s) used to compound the MPA at issue, Liberty Industries, Inc. and its owners, managers, employees, and agents owed a duty to the Plaintiffs to exercise reasonable care when constructing the cleanroom(s).

RESPONSE TO REQUEST FOR ADMISSION NO. 10:

Plaintiffs object to the extent that this RFA requires Plaintiffs to admit to a legal conclusion which is not a permissible use of Rule 36 RFAs. *See e.g., Iantosca v. Benistar Admin Servs., Inc.*, Case No. 08-11785, 2012 U.S. Dist. LEXIS 7896 (D. Mass. 2012); *In re Tobkin*, 578 Fed. Appx. 962 (11th Cir. 2014).

REQUEST FOR ADMISSION NO. 11:

When constructing the cleanroom(s) used to compound the MPA at issue, Liberty Industries, Inc. and its owners, managers, employees, and agents, breached their duty to the Plaintiffs.

RESPONSE TO REQUEST FOR ADMISSION NO. 11:

Plaintiffs object to the extent that this RFA requires Plaintiffs to admit to a legal conclusion which is not a permissible use of Rule 36 RFAs. *See e.g., Iantosca v. Benistar Admin Servs., Inc.*, Case No. 08-11785, 2012 U.S. Dist. LEXIS 7896 (D. Mass. 2012); *In re Tobkin*, 578 Fed. Appx. 962 (11th Cir. 2014).

REQUEST FOR ADMISSION NO. 12:

Liberty Industries, Inc. and its owners, managers, employees, and agents' breach of their duty to the Plaintiffs was a proximate cause of the Plaintiffs' alleged injuries and damages.

RESPONSE TO REQUEST FOR ADMISSION NO. 12:

Plaintiffs object to the extent that this RFA requires Plaintiffs to admit to a legal conclusion which is not a permissible use of Rule 36 RFAs. *See e.g.*, *Iantosca v. Benistar Admin Servs., Inc.*, Case No. 08-11785, 2012 U.S. Dist. LEXIS 7896 (D. Mass. 2012); *In re Tobkin*, 578 Fed. Appx. 962 (11th Cir. 2014).

REQUEST FOR ADMISSION NO. 13:

UniFirst Corporation d/b/a UniClean Cleanroom Services and its owners, managers, employees, and agents owed a duty to the Plaintiffs to exercise reasonable care when servicing NECC's cleanroom(s) used to compound the MPA at issue.

RESPONSE TO REQUEST FOR ADMISSION NO. 13:

Plaintiffs object to the extent that this RFA requires Plaintiffs to admit to a legal conclusion which is not a permissible use of Rule 36 RFAs. *See e.g.*, *Iantosca v. Benistar Admin Servs., Inc.*, Case No. 08-11785, 2012 U.S. Dist. LEXIS 7896 (D. Mass. 2012); *In re Tobkin*, 578 Fed. Appx. 962 (11th Cir. 2014).

REQUEST FOR ADMISSION NO. 14:

UniFirst Corporation d/b/a UniClean Cleanroom Services and its owners, managers, employees, and agents breached their duty to the Plaintiffs when servicing NECC's cleanroom(s) used to compound the MPA at issue.

RESPONSE TO REQUEST FOR ADMISSION NO. 14:

Plaintiffs object to the extent that this RFA requires Plaintiffs to admit to a legal conclusion which is not a permissible use of Rule 36 RFAs. *See e.g., Iantosca v. Benistar Admin Servs., Inc.*, Case No. 08-11785, 2012 U.S. Dist. LEXIS 7896 (D. Mass. 2012); *In re Tobkin*, 578 Fed. Appx. 962 (11th Cir. 2014).

REQUEST FOR ADMISSION NO. 15:

UniFirst Corporation d/b/a UniClean Cleanroom Services and its owners, managers, employees, and agents' breach of their duty to the Plaintiffs was a proximate cause of the Plaintiffs' alleged injuries and damages.

RESPONSE TO REQUEST FOR ADMISSION NO. 15:

Plaintiffs object to the extent that this RFA requires Plaintiffs to admit to a legal conclusion which is not a permissible use of Rule 36 RFAs. *See e.g., Iantosca v. Benistar Admin Servs., Inc.*, Case No. 08-11785, 2012 U.S. Dist. LEXIS 7896 (D. Mass. 2012); *In re Tobkin*, 578 Fed. Appx. 962 (11th Cir. 2014).

REQUEST FOR ADMISSION NO. 16:

ARL Bio Pharma, Inc. d/b/a Analytical Research Laboratories and its owners, managers, employees, and agents owed a duty to the Plaintiffs to exercise reasonable care when conducting sterility testing on MPA from NECC.

RESPONSE TO REQUEST FOR ADMISSION NO. 16:

Plaintiffs object to the extent that this RFA requires Plaintiffs to admit to a legal conclusion which is not a permissible use of Rule 36 RFAs. *See e.g., Iantosca v. Benistar Admin*

Servs., Inc., Case No. 08-11785, 2012 U.S. Dist. LEXIS 7896 (D. Mass. 2012); *In re Tobkin*, 578 Fed. Appx. 962 (11th Cir. 2014).

REQUEST FOR ADMISSION NO. 17:

ARL Bio Pharma, Inc. d/b/a Analytical Research Laboratories and its owners, managers, employees, and agents breached their duty to the Plaintiffs when conducting sterility testing on MPA produced by NECC.

RESPONSE TO REQUEST FOR ADMISSION NO. 17:

Plaintiffs object to the extent that this RFA requires Plaintiffs to admit to a legal conclusion which is not a permissible use of Rule 36 RFAs. *See e.g., Iantosca v. Benistar Admin Servs., Inc.*, Case No. 08-11785, 2012 U.S. Dist. LEXIS 7896 (D. Mass. 2012); *In re Tobkin*, 578 Fed. Appx. 962 (11th Cir. 2014).

REQUEST FOR ADMISSION NO. 18:

ARL Bio Pharma, Inc. d/b/a Analytical Research Laboratories and its owners, managers, employees, and agents' breach of their duty to the Plaintiffs was a proximate cause of the Plaintiffs' alleged injuries and damages.

RESPONSE TO REQUEST FOR ADMISSION NO. 18:

Plaintiffs object to the extent that this RFA requires Plaintiffs to admit to a legal conclusion which is not a permissible use of Rule 36 RFAs. *See e.g., Iantosca v. Benistar Admin Servs., Inc.*, Case No. 08-11785, 2012 U.S. Dist. LEXIS 7896 (D. Mass. 2012); *In re Tobkin*, 578 Fed. Appx. 962 (11th Cir. 2014).

REQUEST FOR ADMISSION NO. 19:

Prior to September 18, 2012, the only information related to the multiple investigations of NECC conducted by the federal Food and Drug Administration ("FDA") and Massachusetts Board of Registration in Pharmacy ("Mass. BoP") available to customers or potential customers of NECC without a federal Freedom of Information Act or Massachusetts Public Records Act request was the FDA's 2006 Warning Letter to NECC.

RESPONSE TO REQUEST FOR ADMISSION NO. 19:

Denied. On information and belief, Plaintiffs believe that other information existed related to the multiple investigations of NECC other than those identified in RFA 19.

REQUEST FOR ADMISSION NO. 20:

The recognized standard of acceptable professional practice did not require a potential customer of NECC to submit a federal Freedom of Information Act or Massachusetts Public Records Act request for information regarding NECC prior to purchasing.

RESPONSE TO REQUEST FOR ADMISSION NO. 20:

Plaintiffs object to the extent that this RFA requires Plaintiffs to admit to a legal conclusion which is not a permissible use of Rule 36 RFAs. *See e.g.*, *Iantosca v. Benistar Admin Servs., Inc.*, Case No. 08-11785, 2012 U.S. Dist. LEXIS 7896 (D. Mass. 2012); *In re Tobkin*, 578 Fed. Appx. 962 (11th Cir. 2014).

REQUEST FOR ADMISSION NO. 21:

The median response time by the FDA to federal Freedom of Information Act requests in calendar year 2011 was between 21 and 40 days for "simple" requests, and between 181 and 200 days for "complex" requests.[1]

RESPONSE TO REQUEST FOR ADMISSION NO. 21:

Plaintiffs' Counsel made reasonable inquiry regarding the matters stated in this request, and the information known or readily obtainable by the Plaintiffs' Counsel is insufficient to enable the Plaintiffs' Counsel to admit or deny this request. The information necessary to respond to this RFA is in the possession of third parties, and Plaintiffs have made a reasonable inquiry as to the documents within its possession, and such information is sufficient to admit or deny. Further, Rule 36 does not impose upon Plaintiffs the duty to investigate or obtain documents within the possession of third parties in order to obtain information necessary to respond to an RFA. *See e.g.*, *Henry v. Champlain Enterprises, Inc.*, 212 F.R.D. 73 (N.D. New York 2003) (collecting cases and authorities).

REQUEST FOR ADMISSION NO. 22:

The FDA's median response time to federal Freedom of Information Act requests in 2012 was between 141 and 160 days for "simple" requests and between 201 and 300 days for "complex" requests.[2]

[1] Exhibit A includes four charts from http://www.foia.gov/data.html which generates reports on response time to federal Freedom of Information Act requests. The data is sorted by response time for each agency and fiscal year. The four charts in Exhibit A were generated on the website by narrowing the terms to FDA data for "simple" and "complex" request response time for 2011 and 2012, respectively. Median response time is readily apparent from the chart data.

RESPONSE TO REQUEST FOR ADMISSION NO. 22:

Plaintiffs' Counsel made reasonable inquiry regarding the matters stated in this request, and the information known or readily obtainable by the Plaintiffs' Counsel is insufficient to enable the Plaintiffs' Counsel to admit or deny this request. The information necessary to respond to this RFA is in the possession of third parties, and Plaintiffs have made a reasonable inquiry as to the documents within its possession, and such information is insufficient to admit or deny. Further, Rule 36 does not impose upon Plaintiffs the duty to investigate or obtain documents within the possession of third parties in order to obtain information necessary to respond to an RFA. *See e.g.*, *Henry v. Champlain Enterprises, Inc.*, 212 F.R.D. 73 (N.D. New York 2003) (collecting cases and authorities).

REQUEST FOR ADMISSION NO. 23:

The FDA's admitted duty is to be "responsible for protecting the public health by assuring the safety, efficacy and security of human and veterinary drugs, biological products, medical devices, our nation's food supply, cosmetics, and products that emit radiation."[3]

RESPONSE TO REQUEST FOR ADMISSION NO. 23:

Admitted that the link provided by Defendants in the footnote to Request for Admission 23 states that the FDA is "responsible for protecting the public health by assuring the safety, efficacy and security of human and veterinary drugs, biological products, medical devices, our

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[2] Exhibit A includes four charts from http://www.foia.gov/data.html which generates reports on response time to federal Freedom of Information Act requests. The data is sorted by response time for each agency and fiscal year. The four charts in Exhibit A were generated on the website by narrowing the terms to FDA data for "simple" and "complex" request response time for 2011 and 2012, respectively. Median response time is readily apparent from the chart data.

[3] *See* the FDA's website at: http://www.fda.gov/aboutfda/whatwedo/default.htm.

nation's food supply, cosmetics, and products that emit radiation." To the extent that the Request for Admission is meant to require the Plaintiffs' Counsel to admit that the aforementioned quote establishes a legal duty upon the FDA, denied. Plaintiffs object to the extent that this RFA requires Plaintiffs to admit to a legal conclusion which is not a permissible use of Rule 36 RFAs. *See e.g.*, *Iantosca v. Benistar Admin Servs., Inc.*, Case No. 08-11785, 2012 U.S. Dist. LEXIS 7896 (D. Mass. 2012); *In re Tobkin*, 578 Fed. Appx. 962 (11th Cir. 2014).

REQUEST FOR ADMISSION NO. 24:

On August 6, 2009, during a speech at the Food and Drug Institute, FDA Commissioner Margaret Hamburg stated:

> When the FDA finds that a firm is significantly out of compliance, we expect a prompt response to our findings. Once the FDA provides inspection findings identifying a serious problem, the firm will generally have no more than fifteen working days in which to respond before the FDA moves ahead with a warning letter or enforcement action. This will help FDA issue warning letters on a timely basis and facilitate prompt corrective action. . . . [T]he FDA will take responsible steps to speed the issuance of warning letters. . . . The FDA is fortunate to have received significant funding increases for the current and next fiscal year that will be devoted to additional inspection and compliance activities that will support the elements of an effective enforcement strategy that I have outlined.[4]

RESPONSE TO REQUEST FOR ADMISSION NO. 24:

Admit that the linked document contains the quotation contained in RFA 24. Plaintiffs object to this RFA to the extent that it seeks to establish that the quotation establishes a legal

[4] http://www.fda.gov/NewsEvents/Speeches/ucm175983.htm; http://oversight.house.gov/wp-content/uploads/2012/06/6-15-2012-report-fdas-contribution-to-the-drug-shortage-crisis.pdf.

duty or breach of that duty on behalf of the FDA because any such RFA would require Plaintiffs to admit to a legal conclusion which is not a permissible use of Rule 36 RFAs. *See e.g., Iantosca v. Benistar Admin Servs., Inc.*, Case No. 08-11785, 2012 U.S. Dist. LEXIS 7896 (D. Mass. 2012); *In re Tobkin*, 578 Fed. Appx. 962 (11th Cir. 2014).

REQUEST FOR ADMISSION NO. 25:

The statement made by Commissioner Hamburg referenced in the preceding Request for Admission is a statement of an office's activities as contemplated by Fed. R. Evid. 803(8).

RESPONSE TO REQUEST FOR ADMISSION NO. 25:

Denied. The aforementioned document is not a record within the meaning of Fed. R. Evid. 803(8).

REQUEST FOR ADMISSION NO. 26:

The FDA and its officers, employees, and agents owed a duty to the Plaintiffs to exercise reasonable care in regulating NECC, and deciding whether to permit NECC to continue to compound and manufacture medication despite repeated complaints and inspections in the years leading up to 2012.

RESPONSE TO REQUEST FOR ADMISSION NO. 26:

Plaintiffs object to the extent that this RFA requires Plaintiffs to admit to a legal conclusion which is not a permissible use of Rule 36 RFAs. *See e.g., Iantosca v. Benistar Admin Servs., Inc.*, Case No. 08-11785, 2012 U.S. Dist. LEXIS 7896 (D. Mass. 2012); *In re Tobkin*, 578 Fed. Appx. 962 (11th Cir. 2014).

REQUEST FOR ADMISSION NO. 27:

The FDA and its officers, employees, and agents breached their duty to the Plaintiffs in regulating NECC and deciding to allow NECC to continue to compound medication despite repeated complaints and inspections in the years leading up to 2012.

RESPONSE TO REQUEST FOR ADMISSION NO. 27:

Plaintiffs object to the extent that this RFA requires Plaintiffs to admit to a legal conclusion which is not a permissible use of Rule 36 RFAs. *See e.g., Iantosca v. Benistar Admin Servs., Inc.*, Case No. 08-11785, 2012 U.S. Dist. LEXIS 7896 (D. Mass. 2012); *In re Tobkin*, 578 Fed. Appx. 962 (11th Cir. 2014).

REQUEST FOR ADMISSION NO. 28:

The FDA and its officers, employees, and agents' breach of their duty to the Plaintiffs was a proximate cause of the Plaintiffs' alleged injuries and damages.

RESPONSE TO REQUEST FOR ADMISSION NO. 28:

Plaintiffs object to the extent that this RFA requires Plaintiffs to admit to a legal conclusion which is not a permissible use of Rule 36 RFAs. *See e.g., Iantosca v. Benistar Admin Servs., Inc.*, Case No. 08-11785, 2012 U.S. Dist. LEXIS 7896 (D. Mass. 2012); *In re Tobkin*, 578 Fed. Appx. 962 (11th Cir. 2014).

REQUEST FOR ADMISSION NO. 29:

Prior to September 18, 2012, NECC violated the FDA Compliance Policy Guidance on Compounding[5] in the following ways:

a. NECC failed to operate in conformance with applicable state law regulating the practice of pharmacy.

b. NECC compounded drug products that were commercially available in the marketplace or that were essentially copies of commercially-available, FDA-approved drug products.

c. NECC used commercial-scale manufacturing or testing equipment when compounding drug products.

RESPONSE TO REQUEST FOR ADMISSION NO. 29:

Plaintiffs object to this RFA because the Request does not identify any specific provisions of the compliance policy which are alleged to be violated. Plaintiffs further object to this RFA because it is vague and unduly burdensome in that the Request is unlimited time and taken literally would require Plaintiffs to investigate events occurring as early as the foundation of NECC. Plaintiffs further object to the extent that this RFA requires Plaintiffs to admit to a legal conclusion which is not a permissible use of Rule 36 RFAs. *See e.g., Iantosca v. Benistar Admin Servs., Inc.*, Case No. 08-11785, 2012 U.S. Dist. LEXIS 7896 (D. Mass. 2012); *In re Tobkin*, 578 Fed. Appx. 962 (11th Cir. 2014).

[5] A copy of the Compliance Policy Guidance on Compounding in effect until December 2013 is attached as Exhibit B.

REQUEST FOR ADMISSION NO. 30:

In the interview published on April 9, 2013, the FDA acknowledged that it had the authority to inspect and enforce Current Good Manufacturing Practices against compounding pharmacies, including NECC, prior to the fungal meningitis outbreak.[6]

RESPONSE TO REQUEST FOR ADMISSION NO. 30:

Plaintiffs object to this RFA because it fails to identify with specificity the interview, the alleged FDA employee, and the statement of an individual does not amount to an FDA-acknowledge statement. Without such information the RFA is vague and cannot be admitted or denied.

REQUEST FOR ADMISSION NO. 31:

Prior to September 18, 2012, the FDA had the authority to inspect, regulate, and, if need be, shut down NECC.

RESPONSE TO REQUEST FOR ADMISSION NO. 31:

Plaintiffs object to the extent that this RFA requires Plaintiffs to admit to a legal conclusion which is not a permissible use of Rule 36 RFAs. *See e.g.*, *Iantosca v. Benistar Admin Servs., Inc.*, Case No. 08-11785, 2012 U.S. Dist. LEXIS 7896 (D. Mass. 2012); *In re Tobkin*, 578 Fed. Appx. 962 (11th Cir. 2014).

REQUEST FOR ADMISSION NO. 32:

If the FDA had shut down the operation of NECC during any of its pre-September 2012 inspections, the outbreak of fungal meningitis would not have occurred.

[6] http://wayback.archive.org/web/20130429051225/http://www.pharmalive.com/fda-acknowledges-we-could-have-done-more-pursue-compounders.

RESPONSE TO REQUEST FOR ADMISSION NO. 32:

Plaintiffs object to this RFA in that it does a request to admit or deny a fact within the scope of Rule 36 and raises a matter of pure speculation. To the extent that a response is required, the matter is denied. The RFA does not specify any time frame and as a result any conclusive statement that action that the FDA shutting down the operations of NECC would be purely speculative. For example, the FDA may have investigated over a decade before the inspection and could have shut NECC down after any such inspection and NECC could have reopened thereafter.

REQUEST FOR ADMISSION NO. 33:

From September 2012 to October 2013, the FDA inspected more than 40 compounding pharmacies.[7]

RESPONSE TO REQUEST FOR ADMISSION NO. 33:

Plaintiffs admit that the referenced website shows that the FDA inspected more than 40 compounding pharmacies during the identified time period.

REQUEST FOR ADMISSION NO. 34:

From September 2012 to October 2013, Congress did not pass any laws altering or expanding the FDA's authority to regulate or inspect compounding pharmacies.

RESPONSE TO REQUEST FOR ADMISSION NO. 34:

Plaintiffs object to this RFA because it is unduly burdensome in that it would require the Plaintiffs to review every bill passed by Congress during the time period to determine whether

[7] http://www.fda.gov/AboutFDA/CentersOffices/OfficeofGlobalRegulatoryOperationsandPolicy/ORA/ORAElectronicReadinpRoom/ucm340853.htm.

they directly or indirectly altered or expanded the FDA's authority to regulate or inspect compounding pharmacies. This RFA further seeks information that is not reasonably calculated to lead to the discovery of admissible evidence and is vague.

REQUEST FOR ADMISSION NO. 35:

For the following years, the FDA had the corresponding budget.

a. 2002 - $1.55 billion.[8]

b. 2003 - $1.65 billion.[9]

c. 2004 - $1.70 billion.[10]

d. 2005 - $1.80 billion.[11]

e. 2006 - $1.88 billion.[12]

f. 2007 - $2.01 billion.[13]

g. 2008 - $2.42 billion.[14]

h. 2009 - $2.69 billion.[15]

i. 2010 - $3.29 billion.[16]

j. 2011 - $3.69 billion.[17]

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[8] *See* the DHHS website at: http://archive.hhs.gov/budget/04budget/fy2004bib.pdf.
[9] *See* the DHHS website at: http://archive.hhs.gov/budget/05budget/fda.html.
[10] *See* the DHHS website at: http://archive.hhs.gov/budget/06budget/overview.html.
[11] *See* the DHHS website at: http://archive.hhs.gov/budget/07budget/fda.html.
[12] *See* the DHHS website at: http://archive.hhs.gov/budget/08budget/2008budgetinbrief.pdf.
[13] *See* the DHHS website at: http://wayback.archive-it.org/3920/20131025141029/http://www.hhs.gov/about/budget/fy2009/fy2009bib.pdf.
[14] *See* the DHHS website at: http://wayback.archive-it.org/3920/20131028125705/http://www.hhs.gov/about/budget/fy2010/fy2010bib.pdf.
[15] *See* the DHHS website at: https://wayback.archive-it.org/3920/20140402145447/http://www.hhs.gov/about/budget/fy2011/fy2011bib.pdf.
[16] *See* the DHHS website at: https://wayback.archive-it.orq/3920/20140402145424/http://www.hhs.qov/about/budget/fy2012/fy2012bib.pdf.

k. 2012 - $3.56 billion.[18]

RESPONSE TO REQUEST FOR ADMISSION NO. 35:

Admit that the referenced documents contain the budget information referenced in RFA 35.

REQUEST FOR ADMISSION NO. 36:

FDA 483 Inspection Reports, an example of which can be found at http://www.fda.gov/downloads/aboutfda/centersoffices/officeofglobalregulatoryoperationsandpolicy/ora/oraelectronicreadingroom/ucm219374.pdf, are records or statements of a public office as contemplated by Fed. R. Evid. 803(8).[19]

RESPONSE TO REQUEST FOR ADMISSION NO. 36:

Plaintiffs admit that an FDA 483 Inspection Report may be a record or statement of a public office as contemplated by Fed. R. Evid. 803(8). Plaintiffs object to this RFA because it is vague as it lacks sufficient detail to allow the Plaintiffs to admit or deny as to any specific such report. The Plaintiffs simply cannot admit or deny that a record is a public record or not a public record without a request specifically identifying any such record.

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[17] *See* the DHHS website at: https://wayback.archive-it.orq/392012014040320323O/http://www.hhs.gov/budget/fy2013/budget-brief- fy2013.pdf.

[18] *See* the DHHS website at: http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Reports/BudgetReports/UCM347422.pdf.

[19] *Sadler v. Advanced Bionics, Inc.*, No. 3:11-cv-00450, 2013 WL 1311148 at *2 (W.D. Ky. Mar. 26, 2013) (holding that FDA Form 483s and Warning Letters are public records as contemplated by Fed. R. Evid. 803(8)).

REQUEST FOR ADMISSION NO. 37:

FDA Warning Letters, an example of which can be found at http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/2009/ucm209222.htm, are records or statements of a public office as contemplated by Fed. R. Evid. 803(8).[20]

RESPONSE TO REQUEST FOR ADMISSION NO. 37:

Plaintiffs admit that an FDA Warning Letter may be a record or statement of a public office as contemplated by Fed. R. Evid. 803(8). Plaintiffs object to this RFA because it is vague as it lacks sufficient detail to allow the Plaintiffs to admit or deny as to any specific such report. The Plaintiffs simply cannot admit or deny that a record is a public record or not a public record without a request specifically identifying any such record.

REQUEST FOR ADMISSION NO. 38:

FDA Enforcement Reports, an example of which can be found at http://www.fda.gov/safety/recalls/enforcementreports/ucm235277.htm, are records or statements of a public office as contemplated by Fed. R. Evid. 803(8).[21]

RESPONSE TO REQUEST FOR ADMISSION NO. 38:

Plaintiffs admit that an Enforcement Report may be a record or statement of a public office as contemplated by Fed. R. Evid. 803(8). Plaintiffs object to this RFA because it is vague as it lacks sufficient detail to allow the Plaintiffs to admit or deny as to any specific such report. The Plaintiffs simply cannot admit or deny that a record is a public record or not a public record without a request specifically identifying any such record.

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[20] *Id.*
[21] *See generally id.*

REQUEST FOR ADMISSION NO. 39:

Exhibit C is a majority staff report drafted by the Committee on Energy and Commerce of the U.S. House of Representatives for the 113th Congress entitled "FDA's Oversight of NECC and Ameridose: A History of Missed Opportunities?"

RESPONSE TO REQUEST FOR ADMISSION NO. 39:

Denied as phrased as the Request as posed mischaracterized the nature of Exhibit C.

REQUEST FOR ADMISSION NO. 40:

Exhibit C is a record or statement of a public office as contemplated by Fed. R. Evid. 803(8).

RESPONSE TO REQUEST FOR ADMISSION NO. 40:

Denied. Exhibit C is not a record or statement of a public office that sets out matters observed while under a legal duty to report or factual findings from a legally authorized investigation. Further, Exhibit C lacks trustworthiness to be admitted under Rule 803(8). See e.g. *City of New York v. Pullman, Inc.*, 662 F.2d 910, 914 (2d Cir. 1981) (finding a UMTA staff report inadmissible hearsay because "by its own terms, . . . [it] was not the final report or finding of a government agency within the meaning of the Rule, but was an 'interim' staff report in the form of a recommendation to the Administrator").

REQUEST FOR ADMISSION NO. 41:

The presentations, emails, letters, press announcements, memoranda, drafts, and inspection requests created by governmental employees, including employees of the FDA,

during the ongoing investigation of NECC, cited within Exhibit C, are all records or statements of a public office as contemplated by Fed. R. Evid. 803(8).

RESPONSE TO REQUEST FOR ADMISSION NO. 41:

Denied.

REQUEST FOR ADMISSION NO. 42:

Before September 18, 2012, a search for information regarding NECC on the FDA website would have identified the FDA's 2006 Warning Letter as the only regulatory action by the FDA against NECC.

RESPONSE TO REQUEST FOR ADMISSION NO. 42:

Plaintiffs object to this Request because it is vague in that it is unlimited time and cannot admit or deny based on the timeframe covered by this RFA. Plaintiffs further object to this Request to the extent that it requires the Plaintiffs to recreate a search that could have been done over two years ago. Plaintiff further objects to this Request because it would require, even if possible, Plaintiffs' Counsel to conduct a search for every day from the time the FDA created its website through September 18, 2012

Subject to and without waiving this objection, Plaintiffs' Counsel made reasonable inquiry regarding the matters stated in this request, and the information known or readily obtainable by the Plaintiffs' Counsel is insufficient to enable the Plaintiffs' Counsel to admit or deny this request. The information necessary to respond to this RFA is in the possession of third parties, and Plaintiffs have made a reasonable inquiry as to the documents within its possession, and such information is insufficient to admit or deny. Further, Rule 36 does not impose upon Plaintiffs the duty to investigate or obtain documents within the possession of third parties in

order to obtain information necessary to respond to an RFA. *See e.g.*, *Henry v. Champlain Enterprises, Inc.*, 212 F.R.D. 73 (N.D. New York 2003) (collecting cases and authorities).

REQUEST FOR ADMISSION NO. 43:

The 2006 Warning Letter from the FDA to NECC does not mention MPA or other steroids compounded by NECC.

RESPONSE TO REQUEST FOR ADMISSION NO. 43:

Admit that the 2006 Warning Letter does not specifically mention MPA or other steroid compounded by NECC, but denied to the extent that these pharmaceuticals are not contemplated by the Warning Letter as it does specifically states that NECC "compounds human prescription drugs in various dosage forms and strengths."

REQUEST FOR ADMISSION NO. 44:

The December 4, 2006, Warning Letter from the FDA to NECC does not state that any medications compounded by NECC were contaminated.

RESPONSE TO REQUEST FOR ADMISSION NO. 44:

Admit that the 2006 Warning Letter does not specifically state that any medications compounded by NECC were determined to be contaminated. However, the December 4, 2006 Warning Letter specifically states that the FDA was concerned that NECC's method of manufacturing of Avastin would cause contamination. Moreover, the letter specifically states that the violations identified in the letter are not "intended to be an all-inclusive list of deficiencies." To the extent that this RFA is meant to establish that the Defendants were not put

on notice about the potential health risks of using NECC products, denied, as the letter extensively details NECC propensity to manufacture drugs that posed "public health risks."

REQUEST FOR ADMISSION NO. 45:

The FDA did not issue a Public Health Alert (or any other specific alert) to health care providers, warning them of the problems at NECC that the FDA identified in the Warning Letter, on December 4, 2006, or on any subsequent date, prior to September 18, 2012.

RESPONSE TO REQUEST FOR ADMISSION NO. 45:

Plaintiffs' Counsel made reasonable inquiry regarding the matters stated in this request, and the information known or readily obtainable by the Plaintiffs' Counsel is insufficient to enable the Plaintiffs' Counsel to admit or deny this request. The information necessary to respond to this RFA is in the possession of third parties, and Plaintiffs have made a reasonable inquiry as to the documents within its possession, and such information is insufficient to admit or deny. Further, Rule 36 does not impose upon Plaintiffs the duty to investigate or obtain documents within the possession of third parties in order to obtain information necessary to respond to an RFA. *See e.g.*, *Henry v. Champlain Enterprises, Inc.*, 212 F.R.D. 73 (N.D. New York 2003) (collecting cases and authorities).

REQUEST FOR ADMISSION NO. 46:

Prior to September 18, 2012, NECC's January 5, 2007, written response to the FDA's December 4, 2006, Warning Letter was not available to customers or potential customers of NECC without sending a federal Freedom of Information Act or Massachusetts Public Records Act request.

RESPONSE TO REQUEST FOR ADMISSION NO. 46:

Denied. For example, customers or potential customers could have obtained the letter from NECC.

REQUEST FOR ADMISSION NO. 47:

Prior to September 18, 2012, the FDA did not take action against NECC after sending the December 4, 2006, Warning Letter, even though the Warning Letter threatened "additional regulatory action without further notice."

RESPONSE TO REQUEST FOR ADMISSION NO. 47:

Plaintiffs' Counsel made reasonable inquiry regarding the matters stated in this request, and the information known or readily obtainable by the Plaintiffs' Counsel is insufficient to enable the Plaintiffs' Counsel to admit or deny this request. The information necessary to respond to this RFA is in the possession of third parties, and Plaintiffs have made a reasonable inquiry as to the documents within its possession, and such information is insufficient to admit or deny. Further, Rule 36 does not impose upon Plaintiffs the duty to investigate or obtain documents within the possession of third parties in order to obtain information necessary to respond to an RFA. *See e.g.*, *Henry v. Champlain Enterprises, Inc.*, 212 F.R.D. 73 (N.D. New York 2003) (collecting cases and authorities).

REQUEST FOR ADMISSION NO. 48:

On June 25, 2007, the FDA received an adverse event report describing a patient who developed severe endophthalmitis requiring surgery, after the patient received Avastin repackaged by NECC.[22]

RESPONSE TO REQUEST FOR ADMISSION NO. 48:

Admitted.

REQUEST FOR ADMISSION NO. 49:

The FDA did not inspect or take action against NECC in response to the adverse event report in Request for Admission 48, despite the FDA's 2006 Warning Letter to NECC stating, "We are especially concerned with the potential microbial contamination associated with splitting Avastin — a single-use, preservative-free, vial — into multiple doses. When used intravitreaily [sic] microbes could cause endophtalmitis [sic] which has a high probability for significant vision loss."[23]

RESPONSE TO REQUEST FOR ADMISSION NO. 49:

Plaintiffs' Counsel made reasonable inquiry regarding the matters stated in this request, and the information known or readily obtainable by the Plaintiffs' Counsel is insufficient to enable the Plaintiffs' Counsel to admit or deny this request. The information necessary to respond to this RFA is in the possession of third parties, and Plaintiffs have made a reasonable inquiry as to the documents within its possession, and such information is insufficient to admit or deny. Further, Rule 36 does not impose upon Plaintiffs the duty to investigate or obtain documents within the possession of third parties in order to obtain information necessary to

[22] *See* Exhibit C.
[23] *See* Exhibit C.

respond to an RFA. *See e.g.*, *Henry v. Champlain Enterprises, Inc.*, 212 F.R.D. 73 (N.D. New York 2003) (collecting cases and authorities).

REQUEST FOR ADMISSION NO. 50:

On June 17, 2008, the FDA received multiple reports regarding betamethasone compounded and distributed by NECC.[24]

RESPONSE TO REQUEST FOR ADMISSION NO. 50:

Admitted.

REQUEST FOR ADMISSION NO. 51:

The FDA Center for Drug Evaluation and Research ("CDER") decided to inspect NECC as a result of the betamethasone reports and a separate report regarding mesotherapy products.[25]

RESPONSE TO REQUEST FOR ADMISSION NO. 51:

Plaintiffs' Counsel made reasonable inquiry regarding the matters stated in this request, and the information known or readily obtainable by the Plaintiffs' Counsel is insufficient to enable the Plaintiffs' Counsel to admit or deny this request. The information necessary to respond to this RFA is in the possession of third parties, and Plaintiffs have made a reasonable inquiry as to the documents within its possession, and such information is insufficient to admit or deny. Further, Rule 36 does not impose upon Plaintiffs the duty to investigate or obtain documents within the possession of third parties in order to obtain information necessary to respond to an RFA. *See e.g.*, *Henry v. Champlain Enterprises, Inc.*, 212 F.R.D. 73 (N.D. New York 2003) (collecting cases and authorities). Plaintiffs further object to this Request to the

[24] *See* Exhibit C.
[25] *See* Exhibit C.

extent that it requires Plaintiffs' Counsel to speculate as to why the FDA decided to take action and fails to identify any time frame when any such decision was or was not made. Any such Request is beyond the requirements of Rule 36.

REQUEST FOR ADMISSION NO. 52:

CDER drafted an inspection assignment for the FDA's New England District Office that was ultimately issued on September 16, 2008.[26]

RESPONSE TO REQUEST FOR ADMISSION NO. 52:

Admitted.

REQUEST FOR ADMISSION NO. 53:

The FDA intended to seek an injunction against NECC if it was still compounding when the inspection referred to in Request for Admission 52 occurred.[27]

RESPONSE TO REQUEST FOR ADMISSION NO. 53:

Plaintiffs' Counsel made reasonable inquiry regarding the matters stated in this request, and the information known or readily obtainable by the Plaintiffs' Counsel is insufficient to enable the Plaintiffs' Counsel to admit or deny this request. The information necessary to respond to this RFA is in the possession of third parties, and Plaintiffs have made a reasonable inquiry as to the documents within its possession, and such information is insufficient to admit or deny. Further, Rule 36 does not impose upon Plaintiffs the duty to investigate or obtain documents within the possession of third parties in order to obtain information necessary to

[26] *See* Exhibit C.
[27] *See* Exhibit C.

respond to an RFA. *See e.g.*, *Henry v. Champlain Enterprises, Inc.*, 212 F.R.D. 73 (N.D. New York 2003) (collecting cases and authorities).

REQUEST FOR ADMISSION NO. 54:

CDER's Division of Manufacturing and Product Quality planned to assist with manufacturing and sterility assurance issues during the inspection referred to in Request for Admission 52.[28]

RESPONSE TO REQUEST FOR ADMISSION NO. 54:

Plaintiffs' Counsel made reasonable inquiry regarding the matters stated in this request, and the information known or readily obtainable by the Plaintiffs' Counsel is insufficient to enable the Plaintiffs' Counsel to admit or deny this request. The information necessary to respond to this RFA is in the possession of third parties, and Plaintiffs have made a reasonable inquiry as to the documents within its possession, and such information is insufficient to admit or deny. Further, Rule 36 does not impose upon Plaintiffs the duty to investigate or obtain documents within the possession of third parties in order to obtain information necessary to respond to an RFA. *See e.g.*, *Henry v. Champlain Enterprises, Inc.*, 212 F.R.D. 73 (N.D. New York 2003) (collecting cases and authorities).

REQUEST FOR ADMISSION NO. 55:

On October 9, 2008, while discussions within the FDA regarding inspecting NECC were ongoing, the Los Angeles District Office of the FDA received a complaint about a patient

[28] *See* Exhibit C.

requiring hospitalization after receiving phosphatidylcholine, a mesotherapy product, from NECC.[29]

RESPONSE TO REQUEST FOR ADMISSION NO. 55:

Admit that the Los Angeles District Office received a complaint on October 9, 2008 about a patient requiring hospitalization after receiving phosphatidylcholine from NECC. As to the admission or denial of any other statement contained in RFA 55, Plaintiffs' Counsel made reasonable inquiry regarding the matters stated in this request, and the information known or readily obtainable by the Plaintiffs' Counsel is insufficient to enable the Plaintiffs' Counsel to admit or deny this request. The information necessary to respond to this RFA is in the possession of third parties, and Plaintiffs have made a reasonable inquiry as to the documents within its possession, and such information is insufficient to admit or deny. Further, Rule 36 does not impose upon Plaintiffs the duty to investigate or obtain documents within the possession of third parties in order to obtain information necessary to respond to an RFA. *See e.g., Henry v. Champlain Enterprises, Inc.*, 212 F.R.D. 73 (N.D. New York 2003) (collecting cases and authorities).

REQUEST FOR ADMISSION NO. 56:

According to the report referenced in Request for Admission 55, after the initial infusion period, the patient "developed [a] burning sensation" and a "swollen arm and hand." After the patient was discharged, he could not swallow food or liquid, vomited, and urinated blood. He

[29] *See* Exhibit C.

was "admitted to an emergency room three more times," and "[t]he physician found blood clots in his arm and hand."[30]

RESPONSE TO REQUEST FOR ADMISSION NO. 56:

Admitted that Exhibit C contains the above-quotations. To the extent that this RFA requests that the Plaintiffs' Counsel admit or deny that these events actually took place, Plaintiffs' Counsel made reasonable inquiry regarding the matters stated in this request, and the information known or readily obtainable by the Plaintiffs' Counsel is insufficient to enable the Plaintiffs' Counsel to admit or deny this request. The information necessary to respond to this RFA is in the possession of third parties, and Plaintiffs have made a reasonable inquiry as to the documents within its possession, and such information is insufficient to admit or deny. Further, Rule 36 does not impose upon Plaintiffs the duty to investigate or obtain documents within the possession of third parties in order to obtain information necessary to respond to an RFA. *See e.g.*, *Henry v. Champlain Enterprises, Inc.*, 212 F.R.D. 73 (N.D. New York 2003) (collecting cases and authorities).

REQUEST FOR ADMISSION NO. 57:

The FDA's New England District Office was informed of the facts described in Requests for Admissions 55-56 on October 16, 2008, and planned to "make sure the investigator follow[ed] up" on the report during the planned inspection of NECC.[31]

[30] *See* Exhibit C.
[31] *See* Exhibit C.

RESPONSE TO REQUEST FOR ADMISSION NO. 57:

Plaintiffs object to this RFA as it is vague in that it is unclear in that the Request does not set forth simply and directly the matters which are to be admitted or denied. Subject to and without waiving this objection, Plaintiffs' Counsel made reasonable inquiry regarding the matters stated in this request, and the information known or readily obtainable by the Plaintiffs' Counsel is insufficient to enable the Plaintiffs' Counsel to admit or deny this request. The information necessary to respond to this RFA is in the possession of third parties, and Plaintiffs have made a reasonable inquiry as to the documents within its possession, and such information is insufficient to admit or deny. Further, Rule 36 does not impose upon Plaintiffs the duty to investigate or obtain documents within the possession of third parties in order to obtain information necessary to respond to an RFA. *See e.g.*, *Henry v. Champlain Enterprises, Inc.*, 212 F.R.D. 73 (N.D. New York 2003) (collecting cases and authorities).

REQUEST FOR ADMISSION NO. 58:

However, according to the compliance officer's notes from a meeting that took place on October 14, 2008, the FDA had already decided to postpone the inspection until the FDA sent a response letter to NECC regarding the 2006 Warning Letter.[32]

RESPONSE TO REQUEST FOR ADMISSION NO. 58:

Plaintiffs object to this Request because Plaintiffs cannot identify any compliance officer's notes from a meeting that took place on October 14, 2008, and therefore Plaintiffs cannot admit or deny this RFA as phrased.

[32] *See* Exhibit C.

REQUEST FOR ADMISSION NO. 59:

Prior to September 18, 2012, the FDA's letter of October 31, 2008, in reply to NECC's response of January 5, 2007, was not available to customers or potential customers of NECC without a federal Freedom of Information Act or Massachusetts Public Records Act request.

RESPONSE TO REQUEST FOR ADMISSION NO. 59:

Denied. For example, customer or potential customers of NECC could have obtained the documents referenced in the RFA from NECC.

REQUEST FOR ADMISSION NO. 60:

The FDA did not perform the follow-up inspection promised in its letter of October 31, 2008, and never returned to inspect NECC until after September 18, 2012.

RESPONSE TO REQUEST FOR ADMISSION NO. 60:

Plaintiffs' Counsel made reasonable inquiry regarding the matters stated in this request, and the information known or readily obtainable by the Plaintiffs' Counsel is insufficient to enable the Plaintiffs' Counsel to admit or deny this request. The information necessary to respond to this RFA is in the possession of third parties, and Plaintiffs have made a reasonable inquiry as to the documents within its possession, and such information is insufficient to admit or deny. Further, Rule 36 does not impose upon Plaintiffs the duty to investigate or obtain documents within the possession of third parties in order to obtain information necessary to respond to an RFA. *See e.g.*, *Henry v. Champlain Enterprises, Inc.*, 212 F.R.D. 73 (N.D. New York 2003) (collecting cases and authorities).

REQUEST FOR ADMISSION NO. 61:

In 2009, the FDA received testing results for the phosphatidylcholine referenced in Requests for Admissions 55-57, confirming the medication was super-potent and displayed signs of degradation.[33]

RESPONSE TO REQUEST FOR ADMISSION NO. 61:

Plaintiffs' Counsel made reasonable inquiry regarding the matters stated in this request, and the information known or readily obtainable by Plaintiffs' Counsel is insufficient to enable Plaintiffs' Counsel to admit or deny this request as the document referenced in the Exhibit cannot be located. Therefore, the information necessary to respond to this RFA is in the possession of third parties, and Plaintiffs have made a reasonable inquiry as to the documents within its possession, and such information is insufficient to admit or deny. Further, Rule 36 does not impose upon Plaintiffs the duty to investigate or obtain documents within the possession of third parties in order to obtain information necessary to respond to an RFA. *See e.g., Henry v. Champlain Enterprises, Inc.*, 212 F.R.D. 73 (N.D. New York 2003) (collecting cases and authorities).

REQUEST FOR ADMISSION NO. 62:

On February 11, 2009, after receiving the testing results described in Request for Admission 61, a New England District compliance officer emailed a number of his colleagues, stating "ODER wants us to immediately (today) go [to] NECC to determine if the firm is willing to recall the Phosphatidyl choline [sic] injection it compounds. The drug is superpotent and not

[33] *See* Exhibit C.

approved and should be recalled. We want to determine the batch size, and where distributed. The recall part should be done immediately and can be separate from the inspection."[34]

RESPONSE TO REQUEST FOR ADMISSION NO. 62:

Admitted that the quoted email appears in the cited Exhibit C. To the extent that the RFA requires Plaintiffs' Counsel to admit or deny whether the events cited in the report ever took place, Plaintiffs' Counsel made reasonable inquiry regarding the matters stated in this request, and the information known or readily obtainable by the Plaintiffs' Counsel is insufficient to enable the Plaintiffs' Counsel to admit or deny this request. The information necessary to respond to this RFA is in the possession of third parties, and Plaintiffs have made a reasonable inquiry as to the documents within its possession, and such information is insufficient to admit or deny. Further, Rule 36 does not impose upon Plaintiffs the duty to investigate or obtain documents within the possession of third parties in order to obtain information necessary to respond to an RFA. *See e.g.*, *Henry v. Champlain Enterprises, Inc.*, 212 F.R.D. 73 (N.D. New York 2003) (collecting cases and authorities).

REQUEST FOR ADMISSION NO. 63:

The recall referred to in Request for Admission 62 did not happen the following day, and, as of February 17, 2009, the FDA had not even informed NECC of the testing results.[35]

RESPONSE TO REQUEST FOR ADMISSION NO. 63:

Plaintiffs' Counsel made reasonable inquiry regarding the matters stated in this request, and the information known or readily obtainable by the Plaintiffs' Counsel is insufficient to

[34] *See* Exhibit C.
[35] *See* Exhibit C.

enable the Plaintiffs' Counsel to admit or deny this request. The information necessary to respond to this RFA is in the possession of third parties, and Plaintiffs have made a reasonable inquiry as to the documents within its possession, and such information is insufficient to admit or deny. Further, Rule 36 does not impose upon Plaintiffs the duty to investigate or obtain documents within the possession of third parties in order to obtain information necessary to respond to an RFA. *See e.g.*, *Henry v. Champlain Enterprises, Inc.*, 212 F.R.D. 73 (N.D. New York 2003) (collecting cases and authorities).

REQUEST FOR ADMISSION NO. 64:

The planned inspection of NECC, which was rescheduled to take place "around March 23, 2009," was postponed for a second time on March 18, 2009, to allow the FDA to broaden the scope of the inspection assignment to establish that NECC was acting as a manufacturer rather than a traditional compounding pharmacy, in anticipation of the FDA having to defend enforcement actions taken against NECC in court, such as the seizure of products or an injunction.[36]

RESPONSE TO REQUEST FOR ADMISSION NO. 64:

Plaintiffs' Counsel made reasonable inquiry regarding the matters stated in this request, and the information known or readily obtainable by the Plaintiffs' Counsel is insufficient to enable the Plaintiffs' Counsel to admit or deny this request. The information necessary to respond to this RFA is in the possession of third parties, and Plaintiffs have made a reasonable inquiry as to the documents within its possession, and such information is insufficient to admit or deny. Further, Rule 36 does not impose upon Plaintiffs the duty to investigate or obtain

[36] *See* Exhibit C.

documents within the possession of third parties in order to obtain information necessary to respond to an RFA. *See e.g.*, *Henry v. Champlain Enterprises, Inc.*, 212 F.R.D. 73 (N.D. New York 2003) (collecting cases and authorities).

REQUEST FOR ADMISSION NO. 65:

Near the end of 2009, the FDA received complaints about NECC's solicitation and distribution of erythromycin without patient-specific prescriptions and NECC's sale of sodium tetradecyl sulfate to a physician in North Carolina for use in treating varicose veins, when there was only one commercially-available product indicated for such treatment.[37]

RESPONSE TO REQUEST FOR ADMISSION NO. 65:

Plaintiffs' Counsel made reasonable inquiry regarding the matters stated in this request, and the information known or readily obtainable by the Plaintiffs' Counsel is insufficient to enable the Plaintiffs' Counsel to admit or deny this request. The information necessary to respond to this RFA is in the possession of third parties, and Plaintiffs have made a reasonable inquiry as to the documents within its possession, and such information is insufficient to admit or deny. Further, Rule 36 does not impose upon Plaintiffs the duty to investigate or obtain documents within the possession of third parties in order to obtain information necessary to respond to an RFA. *See e.g.*, *Henry v. Champlain Enterprises, Inc.*, 212 F.R.D. 73 (N.D. New York 2003) (collecting cases and authorities).

[37] *See* Exhibit C.

REQUEST FOR ADMISSION NO. 66:

According to the complaint report, the FDA was aware that NECC was compounding sodium tetradecyl sulfate and stated that it would be issuing an inspection assignment for NECC "in the future."[38]

RESPONSE TO REQUEST FOR ADMISSION NO. 66:

Denied as phrased as the aforementioned complaint report does not state that the FDA would be issuing an "inspection assignment" for NECC.

REQUEST FOR ADMISSION NO. 67:

In September 2010, the FDA received a report that NECC was soliciting sales of an antibiotic during a shortage, along with a number of other products.[39]

RESPONSE TO REQUEST FOR ADMISSION NO. 67:

Admit that the FDA received a report in September 2010 that NECC was soliciting sales of an antibiotic during a shortage. Denied as to whether sales were also solicited for a "number of other products."

REQUEST FOR ADMISSION NO. 68:

On May 10, 2011, the Denver District Office of the FDA informed the FDA's New England District Office that the Colorado Board of Pharmacy had issued a cease and desist order to NECC.[40]

[38] *See* Exhibit C.
[39] *See* Exhibit C.
[40] *See* Exhibit C.

RESPONSE TO REQUEST FOR ADMISSION NO. 68:

Admit.

REQUEST FOR ADMISSION NO. 69:

As early as May 11, 2011, the FDA had "determined that NECC was a manufacturer, not a compounding pharmacy."[41]

RESPONSE TO REQUEST FOR ADMISSION NO. 69:

Plaintiffs' Counsel made reasonable inquiry regarding the matters stated in this request, and the information known or readily obtainable by the Plaintiffs' Counsel is insufficient to enable the Plaintiffs' Counsel to admit or deny this request. The information necessary to respond to this RFA is in the possession of third parties, and Plaintiffs have made a reasonable inquiry as to the documents within its possession, and such information is insufficient to admit or deny. Further, Rule 36 does not impose upon Plaintiffs the duty to investigate or obtain documents within the possession of third parties in order to obtain information necessary to respond to an RFA. *See e.g.*, *Henry v. Champlain Enterprises, Inc.*, 212 F.R.D. 73 (N.D. New York 2003) (collecting cases and authorities).

REQUEST FOR ADMISSION NO. 70:

Less than two weeks later, on May 24, 2011, the Mass. BoP inspected NECC's facility after NECC updated its facility and moved into adjacent space, and the Mass. BoP allowed NECC to continue to compound medications.

[41] *See* Exhibit C.

RESPONSE TO REQUEST FOR ADMISSION NO. 70:

Plaintiffs' Counsel made reasonable inquiry regarding the matters stated in this request, and the information known or readily obtainable by the Plaintiffs' Counsel is insufficient to enable the Plaintiffs' Counsel to admit or deny this request. The information necessary to respond to this RFA is in the possession of third parties, and Plaintiffs have made a reasonable inquiry as to the documents within its possession, and such information is insufficient to admit or deny. Further, Rule 36 does not impose upon Plaintiffs the duty to investigate or obtain documents within the possession of third parties in order to obtain information necessary to respond to an RFA. *See e.g.*, *Henry v. Champlain Enterprises, Inc.*, 212 F.R.D. 73 (N.D. New York 2003) (collecting cases and authorities).

REQUEST FOR ADMISSION NO. 71:

On July 16, 2012, the Denver District Office of the FDA again contacted the New England District Office to report that NECC had violated the Colorado Board of Pharmacy's cease and desist order.[42]

RESPONSE TO REQUEST FOR ADMISSION NO. 71:

Plaintiffs' Counsel made reasonable inquiry regarding the matters stated in this request, and the information known or readily obtainable by the Plaintiffs' Counsel is insufficient to enable the Plaintiffs' Counsel to admit or deny this request. The information necessary to respond to this RFA is in the possession of third parties, and Plaintiffs have made a reasonable inquiry as to the documents within its possession, and such information is insufficient to admit or deny. Further, Rule 36 does not impose upon Plaintiffs the duty to investigate or obtain

[42] *See* Exhibit C.

documents within the possession of third parties in order to obtain information necessary to respond to an RFA. *See e.g.*, *Henry v. Champlain Enterprises, Inc.*, 212 F.R.D. 73 (N.D. New York 2003) (collecting cases and authorities).

REQUEST FOR ADMISSION NO. 72:

Prior to September 18, 2012, the FDA took no action against NECC in response to the Denver District Office's report.[43]

RESPONSE TO REQUEST FOR ADMISSION NO. 72:

Plaintiffs' Counsel made reasonable inquiry regarding the matters stated in this request, and the information known or readily obtainable by the Plaintiffs' Counsel is insufficient to enable the Plaintiffs' Counsel to admit or deny this request. The information necessary to respond to this RFA is in the possession of third parties, and Plaintiffs have made a reasonable inquiry as to the documents within its possession, and such information is insufficient to admit or deny. Further, Rule 36 does not impose upon Plaintiffs the duty to investigate or obtain documents within the possession of third parties in order to obtain information necessary to respond to an RFA. *See e.g.*, *Henry v. Champlain Enterprises, Inc.*, 212 F.R.D. 73 (N.D. New York 2003) (collecting cases and authorities).

REQUEST FOR ADMISSION NO. 73:

The FDA did not inspect Analytical Research Laboratories prior to November 8, 2012, when the FDA discovered multiple violations related to the testing of NECC medications.

[43] *See* Exhibit C.

RESPONSE TO REQUEST FOR ADMISSION NO. 73:

Plaintiffs' Counsel made reasonable inquiry regarding the matters stated in this request, and the information known or readily obtainable by the Plaintiffs' Counsel is insufficient to enable the Plaintiffs' Counsel to admit or deny this request. The information necessary to respond to this RFA is in the possession of third parties, and Plaintiffs have made a reasonable inquiry as to the documents within its possession, and such information is insufficient to admit or deny. Further, Rule 36 does not impose upon Plaintiffs the duty to investigate or obtain documents within the possession of third parties in order to obtain information necessary to respond to an RFA. *See e.g.*, *Henry v. Champlain Enterprises, Inc.*, 212 F.R.D. 73 (N.D. New York 2003) (collecting cases and authorities).

Moreover, Plaintiffs object to this RFA in that it is unlimited in time and scope and is therefore overly broad and unduly burdensome. Taken literally, this Request requires Plaintiffs to review documents going as far back as the creation of ARL and any such Request is overly broad and unduly burdensome.

REQUEST FOR ADMISSION NO. 74:

Prior to September 18, 2012, the FDA had the authority to inspect Analytical Research Laboratories to ensure it was engaged in safe, proper testing of medications.

RESPONSE TO REQUEST FOR ADMISSION NO. 74:

Plaintiffs object to the extent that this RFA requires Plaintiffs to admit to a legal conclusion which is not a permissible use of Rule 36 RFAs. *See e.g.*, *Iantosca v. Benistar Admin Servs., Inc.*, Case No. 08-11785, 2012 U.S. Dist. LEXIS 7896 (D. Mass. 2012); *In re Tobkin*, 578 Fed. Appx. 962 (11th Cir. 2014).

REQUEST FOR ADMISSION NO. 75:

The publicly-stated mission of the Mass. BoP is:

> To promote, preserve, and protect the public health, safety, and welfare by fostering the provision of quality pharmaceutical care to the citizens of Massachusetts through the regulation of the practice of pharmacy, the operation of pharmacies, and the distribution of prescription drugs in the public interest. The Massachusetts Board of Registration In Pharmacy will assume a leadership role in regulating the practice of pharmacy and act in accordance with the highest standards of ethics, accountability, efficiency, effectiveness, and openness.[44]

RESPONSE TO REQUEST FOR ADMISSION NO. 75:

Plaintiffs' Counsel attempted to access the link provided in Request for Admission No. 75 but was unable to do so. As a result, Plaintiffs' Counsel cannot admit or deny the Request for Admission as posed. Moreover, to the extent the RFA is meant to establish the Mass. Board of Pharmacy's duty to Plaintiffs in this case, Plaintiffs object to this Request because it requires Plaintiffs to admit to a legal conclusion which is not a permissible use of Rule 36 RFAs. *See e.g.*, *Iantosca v. Benistar Admin Servs., Inc.*, Case No. 08-11785, 2012 U.S. Dist. LEXIS 7896 (D. Mass. 2012); *In re Tobkin*, 578 Fed. Appx. 962 (11th Cir. 2014).

REQUEST FOR ADMISSION NO. 76:

The Mass. BoP and its officers, employees, and agents owed a duty to the Plaintiffs to exercise reasonable care in regulating NECC and deciding whether to allow NECC to continue to compound medication despite repeated complaints and inspections before May of 2012.

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[44] *See* the Massachusetts Board of Registration in Pharmacy website at: http://www.mass.gov/eohhs/gov/departments/dph/programs/hcq/dhpl/pharmacy/about/about-the-board.html.

RESPONSE TO REQUEST FOR ADMISSION NO. 76:

Plaintiffs object to the extent that this RFA requires Plaintiffs to admit to a legal conclusion which is not a permissible use of Rule 36 RFAs. *See e.g.*, *Iantosca v. Benistar Admin Servs., Inc.*, Case No. 08-11785, 2012 U.S. Dist. LEXIS 7896 (D. Mass. 2012); *In re Tobkin*, 578 Fed. Appx. 962 (11th Cir. 2014).

REQUEST FOR ADMISSION NO. 77:

The Mass. BoP and its officers, employees, and agents breached their duty to the Plaintiffs in regulating NECC and deciding to continue to permit NECC to compound medication despite repeated complaints and inspections in the years leading up to 2012.

RESPONSE TO REQUEST FOR ADMISSION NO. 77:

Plaintiffs object to the extent that this RFA requires Plaintiffs to admit to a legal conclusion which is not a permissible use of Rule 36 RFAs. *See e.g.*, *Iantosca v. Benistar Admin Servs., Inc.*, Case No. 08-11785, 2012 U.S. Dist. LEXIS 7896 (D. Mass. 2012); *In re Tobkin*, 578 Fed. Appx. 962 (11th Cir. 2014).

REQUEST FOR ADMISSION NO. 78:

The Mass. BoP and its officers, employees, and agents' breach of their duty to the Plaintiffs was a proximate cause of the Plaintiffs' alleged injuries and damages.

RESPONSE TO REQUEST FOR ADMISSION NO. 78:

Plaintiffs object to the extent that this RFA requires Plaintiffs to admit to a legal conclusion which is not a permissible use of Rule 36 RFAs. *See e.g.*, *Iantosca v. Benistar Admin*

Servs., Inc., Case No. 08-11785, 2012 U.S. Dist. LEXIS 7896 (D. Mass. 2012); *In re Tobkin*, 578 Fed. Appx. 962 (11th Cir. 2014).

REQUEST FOR ADMISSION NO. 79:

Prior to September 18, 2012, the Mass. BoP had the authority to inspect, regulate, and, if need be, summarily close NECC.

RESPONSE TO REQUEST FOR ADMISSION NO. 79:

Plaintiffs object to the extent that this RFA requires Plaintiffs to admit to a legal conclusion which is not a permissible use of Rule 36 RFAs. *See e.g.*, *Iantosca v. Benistar Admin Servs., Inc.*, Case No. 08-11785, 2012 U.S. Dist. LEXIS 7896 (D. Mass. 2012); *In re Tobkin*, 578 Fed. Appx. 962 (11th Cir. 2014).

Plaintiffs further object in that the term "summarily close" is vague.

REQUEST FOR ADMISSION NO. 80:

Prior to September 18, 2012, a search on the Mass. BoP website for regulatory actions against NECC, Barry Cadden, Lisa Cadden, and/or Glenn Chin would have revealed no disciplinary actions.[45]

RESPONSE TO REQUEST FOR ADMISSION NO. 80:

Plaintiffs object to this Request to the extent that it requires the Plaintiffs to recreate a search that could have been done over two years ago. Plaintiffs further state that taken literally, this Request requires Plaintiffs' Counsel to search, even if possible, the relevant website for

[45] *See* Office of Edward Markey, Compounding Pharmacies, Compounding Risk at pp. 3-4 (Oct. 29, 2012), *available at* http://www.snmmi.org/files/docs/Compounding%20Pharmacies%20-%20Compounding%20Risk%20FINAL_0_1382017898361_1.pdf (last visited Oct. 8, 2014).

every day that it existed prior to September 18, 2012. Any such Request is unduly burdensome. Plaintiffs further state that Plaintiffs' Counsel made reasonable inquiry regarding the matters stated in this request, and the information known or readily obtainable by the Plaintiffs' Counsel is insufficient to enable the Plaintiffs' Counsel to admit or deny this request. The information necessary to respond to this RFA is in the possession of third parties, and Plaintiffs have made a reasonable inquiry as to the documents within its possession, and such information is insufficient to admit or deny. Further, Rule 36 does not impose upon Plaintiffs the duty to investigate or obtain documents within the possession of third parties in order to obtain information necessary to respond to an RFA. *See e.g., Henry v. Champlain Enterprises, Inc.*, 212 F.R.D. 73 (N.D. New York 2003) (collecting cases and authorities).

REQUEST FOR ADMISSION NO. 81:

In 1999, after receiving a report that NECC had violated Mass. BoP regulations by providing blank prescription pads in its solicitations to doctors, the Mass. BoP initiated an investigation, but allowed NECC to continue to compound medication.

RESPONSE TO REQUEST FOR ADMISSION NO. 81:

Plaintiffs object to this RFA to the extent that it fails to identify the relevant report to which it was referencing. Plaintiffs' Counsel is not in possession of the referenced report and without such reference cannot admit or deny the request as posed. Plaintiffs' Counsel made reasonable inquiry regarding the matters stated in this request, and the information known or readily obtainable by the Plaintiffs' Counsel is insufficient to enable the Plaintiffs' Counsel to admit or deny this request. The information necessary to respond to this RFA is in the possession of third parties, and Plaintiffs have made a reasonable inquiry as to the documents

within its possession, and such information is insufficient to admit or deny. Further, Rule 36 does not impose upon Plaintiffs the duty to investigate or obtain documents within the possession of third parties in order to obtain information necessary to respond to an RFA. *See e.g., Henry v. Champlain Enterprises, Inc.*, 212 F.R.D. 73 (N.D. New York 2003) (collecting cases and authorities).

REQUEST FOR ADMISSION NO. 82:

In 2001, after receiving a report from the Idaho Board of Pharmacy that NECC was soliciting business for drug products which should have been discontinued by the manufacturer, the Mass. BoP initiated an investigation of NECC, but allowed NECC to continue to compound medication.

RESPONSE TO REQUEST FOR ADMISSION NO. 82:

Plaintiffs object to this RFA to the extent that it fails to identify the relevant report to which it was referencing. Plaintiffs' Counsel is not in possession of the referenced report and without such reference cannot admit or deny the request as posed. Plaintiffs' Counsel made reasonable inquiry regarding the matters stated in this request, and the information known or readily obtainable by the Plaintiffs' Counsel is insufficient to enable the Plaintiffs' Counsel to admit or deny this request. The information necessary to respond to this RFA is in the possession of third parties, and Plaintiffs have made a reasonable inquiry as to the documents within its possession, and such information is insufficient to admit or deny. Further, Rule 36 does not impose upon Plaintiffs the duty to investigate or obtain documents within the possession of third parties in order to obtain information necessary to respond to an RFA. *See e.g., Henry v.*

Champlain Enterprises, Inc., 212 F.R.D. 73 (N.D. New York 2003) (collecting cases and authorities).

REQUEST FOR ADMISSION NO. 83:

In 2002, after receiving a report from the Nevada Board of Pharmacy that NECC was selling products to physicians in Nevada which were not approved by the FDA, the Massachusetts Board of Pharmacy initiated an investigation of NECC, but allowed NECC to continue to compound medication.

RESPONSE TO REQUEST FOR ADMISSION NO. 83:

Plaintiffs object to this RFA to the extent that it fails to identify the relevant report to which it was referencing. Plaintiffs' Counsel is not in possession of the referenced report and without such reference cannot admit or deny the request as posed. Plaintiffs' Counsel made reasonable inquiry regarding the matters stated in this request, and the information known or readily obtainable by the Plaintiffs' Counsel is insufficient to enable the Plaintiffs' Counsel to admit or deny this request. The information necessary to respond to this RFA is in the possession of third parties, and Plaintiffs have made a reasonable inquiry as to the documents within its possession, and such information is insufficient to admit or deny. Further, Rule 36 does not impose upon Plaintiffs the duty to investigate or obtain documents within the possession of third parties in order to obtain information necessary to respond to an RFA. *See e.g.*, *Henry v. Champlain Enterprises, Inc.*, 212 F.R.D. 73 (N.D. New York 2003) (collecting cases and authorities).

REQUEST FOR ADMISSION NO. 84:

Between 2002 and 2004, the Mass. BoP received complaints from the boards of pharmacy for the states of Texas, South Dakota, Iowa, and Wisconsin reporting that NECC was illegally soliciting out-of-state prescriptions for office use, but the Mass. BoP allowed NECC to continue to compound medication.

RESPONSE TO REQUEST FOR ADMISSION NO. 84:

Plaintiffs object to this RFA as it is overly broad and unduly burdensome in that it requires Plaintiffs to review all communications from the referenced boards of pharmacy to the Massachusetts Board of Pharmacy during the relevant time period. Plaintiffs state that Plaintiffs' Counsel made reasonable inquiry regarding the matters stated in this request, and the information known or readily obtainable by the Plaintiffs' Counsel is insufficient to enable the Plaintiffs' Counsel to admit or deny this request. The information necessary to respond to this RFA is in the possession of third parties, and Plaintiffs have made a reasonable inquiry as to the documents within its possession, and such information is insufficient to admit or deny. Further, Rule 36 does not impose upon Plaintiffs the duty to investigate or obtain documents within the possession of third parties in order to obtain information necessary to respond to an RFA. *See e.g., Henry v. Champlain Enterprises, Inc.*, 212 F.R.D. 73 (N.D. New York 2003) (collecting cases and authorities).

Further, to the extent that this RFA is meant to reference documents referenced in Exhibit C, those documents do not come from the "boards of pharmacy" from the states identified, but rather come from individual pharmacists. Therefore, to the extent that this is meant to reference those complaints, this RFA is denied.

REQUEST FOR ADMISSION NO. 85:

On February 5, 2003, the FDA and Mass BoP held a joint meeting to review NECC's inspection history and to formulate a joint state-federal strategy regarding NECC; the participants decided that the Mass. BoP would be primarily responsible for achieving safe compounding practices at NECC.

RESPONSE TO REQUEST FOR ADMISSION NO. 85:

Plaintiffs object to this RFA to the extent that it fails to identify the relevant report to which it was referencing. Plaintiffs' Counsel is not in possession of the referenced report and without such reference cannot admit or deny the request as posed. Plaintiffs' Counsel made reasonable inquiry regarding the matters stated in this request, and the information known or readily obtainable by the Plaintiffs' Counsel is insufficient to enable the Plaintiffs' Counsel to admit or deny this request. The information necessary to respond to this RFA is in the possession of third parties, and Plaintiffs have made a reasonable inquiry as to the documents within its possession, and such information is insufficient to admit or deny. Further, Rule 36 does not impose upon Plaintiffs the duty to investigate or obtain documents within the possession of third parties in order to obtain information necessary to respond to an RFA. *See e.g., Henry v. Champlain Enterprises, Inc.*, 212 F.R.D. 73 (N.D. New York 2003) (collecting cases and authorities).

REQUEST FOR ADMISSION NO. 86:

On April 27, 2004, the FDA and Mass BoP conducted a joint inspection of NECC after receiving two (2) new complaints against NECC. The FDA and Mass BoP allowed NECC to continue to compound medication.

RESPONSE TO REQUEST FOR ADMISSION NO. 86:

Plaintiffs object to this RFA to the extent that it fails to identify the relevant report to which it was referencing. Plaintiffs' Counsel is not in possession of the referenced report and without such reference cannot admit or deny the request as posed. Plaintiffs' Counsel made reasonable inquiry regarding the matters stated in this request, and the information known or readily obtainable by the Plaintiffs' Counsel is insufficient to enable the Plaintiffs' Counsel to admit or deny this request. The information necessary to respond to this RFA is in the possession of third parties, and Plaintiffs have made a reasonable inquiry as to the documents within its possession, and such information is insufficient to admit or deny. Further, Rule 36 does not impose upon Plaintiffs the duty to investigate or obtain documents within the possession of third parties in order to obtain information necessary to respond to an RFA. *See e.g., Henry v. Champlain Enterprises, Inc.*, 212 F.R.D. 73 (N.D. New York 2003) (collecting cases and authorities).

REQUEST FOR ADMISSION NO. 87:

On September 23, 2004, the FDA and Mass BoP conducted a joint inspection of NECC after receiving a complaint that NECC was compounding Trypan Blue Dye for use as a capillary stain during ophthalmic procedures, which was not an approved use. The FDA and Mass BoP allowed NECC to continue to compound medication.

RESPONSE TO REQUEST FOR ADMISSION NO. 87:

Plaintiffs object to this RFA to the extent that it fails to identify the relevant report to which it was referencing. Plaintiffs' Counsel is not in possession of the referenced report and without such reference cannot admit or deny the request as posed. Plaintiffs' Counsel made

reasonable inquiry regarding the matters stated in this request, and the information known or readily obtainable by the Plaintiffs' Counsel is insufficient to enable the Plaintiffs' Counsel to admit or deny this request. The information necessary to respond to this RFA is in the possession of third parties, and Plaintiffs have made a reasonable inquiry as to the documents within its possession, and such information is insufficient to admit or deny. Further, Rule 36 does not impose upon Plaintiffs the duty to investigate or obtain documents within the possession of third parties in order to obtain information necessary to respond to an RFA. *See e.g.*, *Henry v. Champlain Enterprises, Inc.*, 212 F.R.D. 73 (N.D. New York 2003) (collecting cases and authorities).

REQUEST FOR ADMISSION NO. 88:

In calendar year 2006, Pharmacy Support, Inc. conducted two (2) independent audits of NECC, both identifying multiple problems at NECC, but the Mass. BoP allowed NECC to continue to compound medication.

RESPONSE TO REQUEST FOR ADMISSION NO. 88:

Plaintiffs object to this RFA to the extent that it fails to identify the relevant report to which it was referencing. Plaintiffs' Counsel is not in possession of the referenced report and without such reference cannot admit or deny the request as posed. Plaintiffs' Counsel made reasonable inquiry regarding the matters stated in this request, and the information known or readily obtainable by the Plaintiffs' Counsel is insufficient to enable the Plaintiffs' Counsel to admit or deny this request. The information necessary to respond to this RFA is in the possession of third parties, and Plaintiffs have made a reasonable inquiry as to the documents within its possession, and such information is insufficient to admit or deny. Further, Rule 36

does not impose upon Plaintiffs the duty to investigate or obtain documents within the possession of third parties in order to obtain information necessary to respond to an RFA. *See e.g., Henry v. Champlain Enterprises, Inc.*, 212 F.R.D. 73 (N.D. New York 2003) (collecting cases and authorities).

REQUEST FOR ADMISSION NO. 89:

In July 2011, the Mass. BoP was notified that NECC had violated a cease and desist order issued by the Colorado Board of Pharmacy; the Mass. BoP allowed NECC to continue to compound medication.

RESPONSE TO REQUEST FOR ADMISSION NO. 89:

Plaintiffs' Counsel made reasonable inquiry regarding the matters stated in this request, and the information known or readily obtainable by the Plaintiffs' Counsel is insufficient to enable the Plaintiffs' Counsel to admit or deny this request. The information necessary to respond to this RFA is in the possession of third parties, and Plaintiffs have made a reasonable inquiry as to the documents within its possession, and such information is insufficient to admit or deny. Further, Rule 36 does not impose upon Plaintiffs the duty to investigate or obtain documents within the possession of third parties in order to obtain information necessary to respond to an RFA. *See e.g., Henry v. Champlain Enterprises, Inc.*, 212 F.R.D. 73 (N.D. New York 2003) (collecting cases and authorities).

REQUEST FOR ADMISSION NO. 90:

Prior to September 18, 2012, the DEA had the authority to inspect, regulate, and, if need be, revoke NECC's "practitioner" registration.

RESPONSE TO REQUEST FOR ADMISSION NO. 90:

Plaintiffs object to the extent that this RFA requires Plaintiffs to admit to a legal conclusion which is not a permissible use of Rule 36 RFAs. *See e.g., Iantosca v. Benistar Admin Servs., Inc.*, Case No. 08-11785, 2012 U.S. Dist. LEXIS 7896 (D. Mass. 2012); *In re Tobkin*, 578 Fed. Appx. 962 (11th Cir. 2014).

REQUEST FOR ADMISSION NO. 91:

Prior to September 18, 2012, the Tennessee Board of Pharmacy had the authority to inspect, regulate, and, if need be, revoke NECC's Tennessee license.

RESPONSE TO REQUEST FOR ADMISSION NO. 91:

Plaintiffs object to the extent that this RFA requires Plaintiffs to admit to a legal conclusion which is not a permissible use of Rule 36 RFAs. *See e.g., Iantosca v. Benistar Admin Servs., Inc.*, Case No. 08-11785, 2012 U.S. Dist. LEXIS 7896 (D. Mass. 2012); *In re Tobkin*, 578 Fed. Appx. 962 (11th Cir. 2014).

REQUEST FOR ADMISSION NO. 92:

Prior to September 18, 2012, every state that issued a license to NECC had the authority to inspect, regulate, and, if need be, publicly revoke NECC's license.

RESPONSE TO REQUEST FOR ADMISSION NO. 92:

Plaintiffs object to the extent that this RFA requires Plaintiffs to admit to a legal conclusion which is not a permissible use of Rule 36 RFAs. *See e.g., Iantosca v. Benistar Admin Servs., Inc.*, Case No. 08-11785, 2012 U.S. Dist. LEXIS 7896 (D. Mass. 2012); *In re Tobkin*, 578 Fed. Appx. 962 (11th Cir. 2014).

REQUEST FOR ADMISSION NO. 93:

Dr. John Dreyzehner, Commissioner of the Tennessee Department of Health confirmed that the Tennessee Department of Health initially instructed Saint Thomas Outpatient Neurosurgical Center, LLC not to mention meningitis when contacting patients.[46]

RESPONSE TO REQUEST FOR ADMISSION NO. 93:

Denied as phrased because the referenced document is insufficient to allow Plaintiffs to admit or deny the Request. The referenced document is a purported phone conversation between a reporter and an unnamed individual and nowhere in the document or recording does the non-reporter person identify himself as Dr. John Dreyzehner.

REQUEST FOR ADMISSION NO. 94:

The FDA issued the corresponding number of Warning Letters in each of the years reflected in the columns below

a) 1998 — 814

b) 1999 — 979

c) 2000 — 1,188

d) 2001 — 1,366

e) 2002 — 724

f) 2003 — 676

g) 2004 — 716

h) 2005 — 508

i) 2006 — 468

[46] Review recorded statement attached as Exhibit D.

j) 2007 — 376

k) 2008 — 438

l) 2009 — 572

m) 2010 — 619

n) 2011 — 746

o) 2012 — 733.[47]

RESPONSE TO REQUEST FOR ADMISSION NO. 94:

Plaintiffs object to this Request because it seeks information that is not reasonably calculated to lead to the discovery of admissible evidence is overly broad, unduly burdensome, and not otherwise discoverable under Rule 26. To the extent that a response is required, the RFA is denied because the referenced document does not contain the information referenced in RFA 94.

REQUEST FOR ADMISSION NO. 95:

Teva Pharmaceuticals USA, Inc. ("Teva") is an FDA-registered manufacturer that manufactured MPA.

RESPONSE TO REQUEST FOR ADMISSION NO. 95:

Admit that an entity listed as "Teva Pharmaceuticals USA, Inc. is listed on the FDA's "Drug Establishments Current Registration Site." After making reasonable inquiry, Plaintiffs' Counsel is without sufficient information to admit or deny any other statement in this Request.

REQUEST FOR ADMISSION NO. 96:

In January 2011 and March 2012, the FDA issued Warning Letters to Teva.

[47] *See* the DHH website at: http://www.hhs.gov/budget/fy2014/fy-2014-budget-in-brief.pdf.

RESPONSE TO REQUEST FOR ADMISSION NO. 96:

Admitted that the FDA website shows that in January 2011 and March 2012 that the FDA issued Warning Letters to Teva.

REQUEST FOR ADMISSION NO. 97:

On September 26, 2007, Teva recalled 80,254 vials of MPA injectable suspension for lack of sterility assurance.[48]

RESPONSE TO REQUEST FOR ADMISSION NO. 97:

Admit that the FDA's website reflects that a recall of 80,254 vials of methylprednisolone acetate injectable suspension was initiated by letter on September 26, 2007 by TEVA Pharmaceuticals USA, Inc. with the stated reason "lack of assurance of sterility." However, based on information known or readily attainable, and after making reasonable inquiry, Plaintiffs' Counsel lacks sufficient information to admit or deny the remainder of this request. Accordingly, except as is consistent with the above, this request is denied.

REQUEST FOR ADMISSION NO. 98:

On March 10, 2011, Teva recalled 1,745,836 bottles and blister packs of methylprednisolone tablets based on the potential of not meeting the Impurity C specification through the product shelf life.[49]

RESPONSE TO REQUEST FOR ADMISSION NO. 98:

Admit that the FDA's website reflects that a recall of 1,745,836 "Methylprednisolone Tablets USP, 4 mg, a) 21-count blister pack (NDC 0555-0301-38), b) 100-count bottle (NDC

[48] http://www.fda.gov/Safety/Recalls/EnforcementReports/2007/ucm120479.htm.
[49] http://www.fda.gov/Safety/Recalls/EnforcementReports/ucm261438.htm.

0555-0301-02)" was initiated by letters on March 10, 2011 by TEVA Pharmaceuticals USA, Inc. with the stated reason "impurities/degradation product; product is being recalled due to the potential of not meeting the Impurity C specification through the product shelf life." However, based on information known or readily attainable, and after making reasonable inquiry, Plaintiffs' Counsel lacks sufficient information to admit or deny the remainder of this request. Accordingly, except as is consistent with the above, this request is denied.

REQUEST FOR ADMISSION NO. 99:

In October 2009, Teva recalled 1,138,800 vials of Propofol Injectable Emulsion for lack of sterility assurance.[50]

RESPONSE TO REQUEST FOR ADMISSION NO. 99:

Admit that the FDA's website reflects that a recall of 1,138,800 vials of Propofol Injectable Emulsion was initiated by letters on October 27, 2009 and October 28, 2009 by TEVA Pharmaceuticals USA, Inc. with the stated reason "lack of sterility assurance: The product was manufactured on equipment found to be contaminated with microbiological organisms." However, based on information known or readily attainable, and after making reasonable inquiry, Plaintiffs' Counsel lacks sufficient information to admit or deny the remainder of this request. Accordingly, except as is consistent with the above, this request is denied.

REQUEST FOR ADMISSION NO. 100:

On April 28, 2010, Teva recalled 750,310 vials of L-Cysteine Hydrochloride Injection due to indications of impurities.[51]

[50] http://www.fda.gov/Safety/Recalls/EnforcementReports/ucm193723.htm.

RESPONSE TO REQUEST FOR ADMISSION NO. 100:

Admit that the FDA's website reflects that a recall of 750,310 vials of L-Cysteine Hydrochloride Injection was initiated by letters on April 28, 2010 by TEVA Pharmaceuticals USA, Inc. with the stated reason "CGMP Deviation: Absence of stability indicating methods for assay and impurities." However, based on information known or readily attainable, and after making reasonable inquiry, Plaintiffs' Counsel lacks sufficient information to admit or deny the remainder of this request. Accordingly, except as is consistent with the above, this request is denied.

REQUEST FOR ADMISSION NO. 101:

Sandoz, Inc. ("Sandoz") is an FDA-registered manufacturer that manufactured MPA.

RESPONSE TO REQUEST FOR ADMISSION NO. 101:

Admitted that an entity listed as "Sandoz, Inc." is listed on the FDA's "Drug Establishments Current Registration Site." After making reasonable inquiry, Plaintiffs' Counsel is without sufficient information to admit or deny any other statement in this Request.

REQUEST FOR ADMISSION NO. 102:

In May 2006, the FDA issued a Warning Letter to Sandoz.

RESPONSE TO REQUEST FOR ADMISSION NO. 102:

Plaintiffs admit that the FDA website shows that in May of 2006 the FDA issued a Warning Letter to Sandoz.

[51] http://www.fda.gov/Safety/Recalls/EnforcementReports/ucm225223.htm.

REQUEST FOR ADMISSION NO. 103:

On March 5, 2010, Sandoz recalled 35,235 vials of MPA because vials were mislabeled to indicate a 24-month useful life, when the proper useful life was 18 months.

RESPONSE TO REQUEST FOR ADMISSION NO. 103:

Admit that the FDA's website reflects that a recall of 35,235 vials of methylprednisolone acetate injectable suspension was initiated by letter on March 5, 2010 by Sandoz, Inc. with the stated reason "Methylprednisolone Acetate in the 40 and 80 mg, single dose lots were mistakenly labeled with a 24 month expiration date instead of 18 months" However, based on information known or readily attainable, and after making reasonable inquiry, Plaintiffs' Counsel lacks sufficient information to admit or deny the remainder of this request. Accordingly, except as is consistent with the above, this request is denied.

REQUEST FOR ADMISSION NO. 104:

On February 24, 2006, Sandoz recalled 379,975 vials of Cefazolin for lack of sterility assurance.[52]

RESPONSE TO REQUEST FOR ADMISSION NO. 104:

Admit that the FDA's website reflects that a recall of 379,975 – 1 g/10mL vials of Cefazolin for Injection was initiated by press release and letter on February 24, 2006 by G. C. Hanford Manufacturing Co. with the stated reason "Non Sterility: Finished product lots lack sterility assurance because certain lots of the bulk API were found to have microbial contamination." However, based on information known or readily attainable, and after making reasonable inquiry, Plaintiffs' Counsel lacks sufficient information to admit or deny the

[52] http://www.fda.gov/Safety/Recalls/EnforcementReports/2006/ucm120397.htm.

remainder of this request. Accordingly, except as is consistent with the above, this request is denied.

REQUEST FOR ADMISSION NO. 105:

On November 17, 2011, Sandoz recalled 4,397 cartons of Enoxaparin Sodium Injection for lack of sterility assurance.[53]

RESPONSE TO REQUEST FOR ADMISSION NO. 105:

Admit that the FDA's website reflects that a recall of 4,397 cartons of Enoxaparin Sodium Injection was initiated by letter on November 17, 2011 by Sandoz, Inc. with the stated reason "Lack of Assurance of Sterility: Needle of packaged pre-filled syringes may be protruding through the needle guard." However, based on information known or readily attainable, and after making reasonable inquiry, Plaintiffs' Counsel lacks sufficient information to admit or deny the remainder of this request. Accordingly, except as is consistent with the above, this request is denied.

REQUEST FOR ADMISSION NO. 106:

In January 2012, Sandoz recalled 2,024 bottles of Cefprozil Powder for Oral Suspension for failure to comply with current good manufacturing practices.[54]

RESPONSE TO REQUEST FOR ADMISSION NO. 106:

Admit that the FDA's website reflects that a recall of 2,024 bottles of Cefprozil Powder for Oral Suspension was initiated by letter dated January 2012 by Sandoz, Inc. with the stated reason "CGMP Deviations: Batches lack manufacturing validation." However, based on

[53] http://www.fda.gov/Safety/Recalls/EnforcementReports/ucm282859.htm.
[54] http://www.fda.gov/Safety/Recalls/EnforcementReports/ucm294071.htm.

information known or readily attainable, and after making reasonable inquiry, Plaintiffs' Counsel lacks sufficient information to admit or deny the remainder of this request. Accordingly, except as is consistent with the above, this request is denied.

REQUEST FOR ADMISSION NO. 107:

Pharmacia and Upjohn, a subsidiary of Pfizer, is an FDA-registered manufacturer of MPA.

RESPONSE TO REQUEST FOR ADMISSION NO. 107:

Denied as phrased.

REQUEST FOR ADMISSION NO. 108:

The FDA issued Warning Letters to Pfizer, or wholly owned subsidiaries, in July 2007, April 2008, April 2009, April 2010, August, 2011, May 2012, and June 2012.

RESPONSE TO REQUEST FOR ADMISSION NO. 108:

Plaintiffs object to this RFA in that it fails to sufficiently identify the "wholly owned subsidiaries" referenced in the RFA and therefore the Request is unduly burdensome and overly broad to the extent that it requires Plaintiffs to research every wholly owned subsidiary of Pfizer and review whether any such entity was issues a warning letter in the referenced time. After making a reasonable inquiry, Plaintiffs are without sufficient information to admit or deny the Request as posed.

REQUEST FOR ADMISSION NO. 109:

On June 24, 2010, Pharmacia and Upjohn, recalled 5,821 tablets of methylprednisolone for failure to meet assay specifications for product stability.[55]

RESPONSE TO REQUEST FOR ADMISSION NO. 109:

Admit that the FDA's website reflects that a recall of 5,821 Medrol, methylprednisolone acetate tablets was initiated by letters dated June 24, 2010 by Pharmacia and Upjohn Company, Div. of Pfizer, Inc., with the stated reason "Subpotent (Single Ingredient Drug):The firm voluntarily initiated this recall when it was determined that this lot did not meet assay specifications on stability." However, based on information known or readily attainable, and after making reasonable inquiry, Plaintiffs' Counsel lacks sufficient information to admit or deny the remainder of this request. Accordingly, except as is consistent with the above, this request is denied.

REQUEST FOR ADMISSION NO. 110:

Compounding pharmacies compound medications for drug companies for use in clinical trials.[56] [57]

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[55] http://www.fda.gov/safety/recalls/enforcementreports/ucm234282.htm.

[56] FDA Compliance Policy Guidance on Pharmacy Compounding, CPG Sec. 460.200:

> In determining whether to initiate such an action, the Agency will consider whether the pharmacy engages in any of the following acts:
>
> ...
>
> 3. Compounding finished drugs from bulk active ingredients that are not components of FDA approved drugs without an FDA sanctioned investigational new drug application (IND) in accordance with 21 U.S.C. § 355(i) and 21 CFR 312.

RESPONSE TO REQUEST FOR ADMISSION NO. 110:

Plaintiffs object to this RFA because it is vague, ambiguous, and does not identify which compounding pharmacies and/or drug manufacturers that compound medications for use in clinical trials. Subject to and without waiving these objections, Plaintiffs state that Plaintiffs' Counsel made reasonable inquiry regarding the matters stated in this request, and the information known or readily obtainable by the Plaintiffs' Counsel is insufficient to enable the Plaintiffs' Counsel to admit or deny this request. The information necessary to respond to this RFA is in the possession of third parties, and Plaintiffs have made a reasonable inquiry as to the documents within its possession, and such information is insufficient to admit or deny. Further, Rule 36 does not impose upon Plaintiffs the duty to investigate or obtain documents within the possession of third parties in order to obtain information necessary to respond to an RFA. See e.g., *Henry v. Champlain Enterprises, Inc.*, 212 F.R.D. 73 (N.D. New York 2003) (collecting cases and authorities).

REQUEST FOR ADMISSION NO. 111:

Exhibit E is an April 10, 2013, report from the Department of Health Human Services, Office of Inspector General titled "High-Risk Compounded Sterile Preparations and Outsourcing by Hospitals That Use Them, OEI-01-13-00150" addressed to Margaret Hamburg, MD, Commissioner of the FDA.

[57] *E.g.*, http://www.restorehc.com/clinical-trials; http://www.mcguffpharmacy.com/ClinicalTrials/ClinicalTrialsHome.aspx.

RESPONSE TO REQUEST FOR ADMISSION NO. 111:

Admitted that Exhibit E is dated April 10, 2013 and appears to be a report from the Department of Health Human Services, Office of Inspector General titled "High-Risk Compounded Sterile Preparations and Outsourcing by Hospitals That Use Them, OEI-01-13-00150" addressed to Margaret Hamburg, MD, Commissioner of the FDA.

REQUEST FOR ADMISSION NO. 112:

Exhibit E is a record or statement of a public office as contemplated by Fed. R. Evid. 803(8).

RESPONSE TO REQUEST FOR ADMISSION NO. 112:

Denied. The attached document lacks the trustworthiness required of Rule 803(8) to be admitted under Rule 803(8) and is not a record or statement as used in Rule 803(8) nor is it reference matters that were observed while "under a legal duty to report".

REQUEST FOR ADMISSION NO. 113:

The report attached as Exhibit E is reliable.

RESPONSE TO REQUEST FOR ADMISSION NO. 113:

Denied.

REQUEST FOR ADMISSION NO. 114:

Ninety-two percent (92%) of a representative sample of acute-care hospitals participating in Medicare used compounded sterile preparations in 2012.[58]

[58] Exhibit E.

RESPONSE TO REQUEST FOR ADMISSION NO. 114:

Plaintiffs object to this RFA as overly broad and unduly burdensome in that it requires Plaintiffs to conduct a survey of a "representative sample of acute-care hospitals participating in Medicare." Plaintiffs further object because there is insufficient information available as to determine whether any survey was conducted with a sufficient sample to be considered a "representative sample" and Plaintiffs are not in possession of sufficient information to admit or deny. Plaintiffs further state that Plaintiffs' Counsel made reasonable inquiry regarding the matters stated in this request, and the information known or readily obtainable by the Plaintiffs' Counsel is insufficient to enable the Plaintiffs' Counsel to admit or deny this request. The information necessary to respond to this RFA is in the possession of third parties, and Plaintiffs have made a reasonable inquiry as to the documents within its possession, and such information is insufficient to admit or deny. Further, Rule 36 does not impose upon Plaintiffs the duty to investigate or obtain documents within the possession of third parties in order to obtain information necessary to respond to an RFA. *See e.g.*, *Henry v. Champlain Enterprises, Inc.*, 212 F.R.D. 73 (N.D. New York 2003) (collecting cases and authorities).

REQUEST FOR ADMISSION NO. 115:

Seventy-nine-point-four percent (79.4%) of a representative sample of acute-care hospitals participating in Medicare that used compounded sterile preparations outsourced the compounding to a supplier.[59]

[59] Exhibit E.

RESPONSE TO REQUEST FOR ADMISSION NO. 115:

Plaintiffs object to this RFA as overly broad and unduly burdensome in that it requires Plaintiffs to conduct a survey of a "representative sample of acute-care hospitals participating in Medicare." Plaintiffs further object because there is insufficient information available as to determine whether any survey was conducted with a sufficient sample to be considered a "representative sample" and Plaintiffs are not in possession of sufficient information to admit or deny. Plaintiffs further state that Plaintiffs' Counsel made reasonable inquiry regarding the matters stated in this request, and the information known or readily obtainable by the Plaintiffs' Counsel is insufficient to enable the Plaintiffs' Counsel to admit or deny this request. The information necessary to respond to this RFA is in the possession of third parties, and Plaintiffs have made a reasonable inquiry as to the documents within its possession, and such information is insufficient to admit or deny. Further, Rule 36 does not impose upon Plaintiffs the duty to investigate or obtain documents within the possession of third parties in order to obtain information necessary to respond to an RFA. *See e.g.*, *Henry v. Champlain Enterprises, Inc.*, 212 F.R.D. 73 (N.D. New York 2003) (collecting cases and authorities).

REQUEST FOR ADMISSION NO. 116:

Sixty-eight-point-one percent (68.1%) of a representative sample of acute-care hospitals participating in Medicare reported that shortages of commercial products were a very important factor when deciding whether to outsource compounded sterile preparations.[60]

[60] Exhibit E.

RESPONSE TO REQUEST FOR ADMISSION NO. 116:

Plaintiffs object to this RFA as overly broad and unduly burdensome in that it requires Plaintiffs to conduct a survey of a "representative sample of acute-care hospitals participating in Medicare." Plaintiffs further object because there is insufficient information available as to determine whether any survey was conducted with a sufficient sample to be considered a "representative sample" and Plaintiffs are not in possession of sufficient information to admit or deny. Plaintiffs further state that Plaintiffs' Counsel made reasonable inquiry regarding the matters stated in this request, and the information known or readily obtainable by the Plaintiffs' Counsel is insufficient to enable the Plaintiffs' Counsel to admit or deny this request. The information necessary to respond to this RFA is in the possession of third parties, and Plaintiffs have made a reasonable inquiry as to the documents within its possession, and such information is insufficient to admit or deny. Further, Rule 36 does not impose upon Plaintiffs the duty to investigate or obtain documents within the possession of third parties in order to obtain information necessary to respond to an RFA. *See e.g.*, *Henry v. Champlain Enterprises, Inc.*, 212 F.R.D. 73 (N.D. New York 2003) (collecting cases and authorities).

REQUEST FOR ADMISSION NO. 117:

Ninety-point-eight percent (90.8%) of a representative sample of acute-care hospitals participating in Medicare reported that shortages of commercial products was a very important or somewhat important factor when deciding whether to outsource compounded sterile preparations.[61]

[61] Exhibit E.

RESPONSE TO REQUEST FOR ADMISSION NO. 117:

Plaintiffs object to this RFA as overly broad and unduly burdensome in that it requires Plaintiffs to conduct a survey of a "representative sample of acute-care hospitals participating in Medicare." Plaintiffs further object because there is insufficient information available as to determine whether any survey was conducted with a sufficient sample to be considered a "representative sample" and Plaintiffs are not in possession of sufficient information to admit or deny. Plaintiffs further state that Plaintiffs' Counsel made reasonable inquiry regarding the matters stated in this request, and the information known or readily obtainable by the Plaintiffs' Counsel is insufficient to enable the Plaintiffs' Counsel to admit or deny this request. The information necessary to respond to this RFA is in the possession of third parties, and Plaintiffs have made a reasonable inquiry as to the documents within its possession, and such information is insufficient to admit or deny. Further, Rule 36 does not impose upon Plaintiffs the duty to investigate or obtain documents within the possession of third parties in order to obtain information necessary to respond to an RFA. *See e.g.*, *Henry v. Champlain Enterprises, Inc.*, 212 F.R.D. 73 (N.D. New York 2003) (collecting cases and authorities).

REQUEST FOR ADMISSION NO. 118:

Seventy-six-point-three percent (76.3%) of a representative sample of acute-care hospitals participating in Medicare reported that the need for special products was a very important or somewhat important factor when deciding whether to outsource compounded sterile preparations.[62]

[62] Exhibit E.

RESPONSE TO REQUEST FOR ADMISSION NO. 118:

Plaintiffs object to this RFA as overly broad and unduly burdensome in that it requires Plaintiffs to conduct a survey of a "representative sample of acute-care hospitals participating in Medicare." Plaintiffs further object because there is insufficient information available as to determine whether any survey was conducted with a sufficient sample to be considered a "representative sample" and Plaintiffs are not in possession of sufficient information to admit or deny. Plaintiffs further state that Plaintiffs' Counsel made reasonable inquiry regarding the matters stated in this request, and the information known or readily obtainable by the Plaintiffs' Counsel is insufficient to enable the Plaintiffs' Counsel to admit or deny this request. The information necessary to respond to this RFA is in the possession of third parties, and Plaintiffs have made a reasonable inquiry as to the documents within its possession, and such information is insufficient to admit or deny. Further, Rule 36 does not impose upon Plaintiffs the duty to investigate or obtain documents within the possession of third parties in order to obtain information necessary to respond to an RFA. *See e.g.*, *Henry v. Champlain Enterprises, Inc.*, 212 F.R.D. 73 (N.D. New York 2003) (collecting cases and authorities).

REQUEST FOR ADMISSION NO. 119:

Eighty-five-point-nine percent (85.9%) of a representative sample of acute-care hospitals participating in Medicare reported that product cost was a very important or somewhat important factor when selecting a particular outside pharmacy to compound sterile preparations.[63]

[63] Exhibit E.

RESPONSE TO REQUEST FOR ADMISSION NO. 119:

Plaintiffs object to this RFA as overly broad and unduly burdensome in that it requires Plaintiffs to conduct a survey of a "representative sample of acute-care hospitals participating in Medicare." Plaintiffs further object because there is insufficient information available as to determine whether any survey was conducted with a sufficient sample to be considered a "representative sample" and Plaintiffs are not in possession of sufficient information to admit or deny. Plaintiffs further state that Plaintiffs' Counsel made reasonable inquiry regarding the matters stated in this request, and the information known or readily obtainable by the Plaintiffs' Counsel is insufficient to enable the Plaintiffs' Counsel to admit or deny this request. The information necessary to respond to this RFA is in the possession of third parties, and Plaintiffs have made a reasonable inquiry as to the documents within its possession, and such information is insufficient to admit or deny. Further, Rule 36 does not impose upon Plaintiffs the duty to investigate or obtain documents within the possession of third parties in order to obtain information necessary to respond to an RFA. *See e.g.*, *Henry v. Champlain Enterprises, Inc.*, 212 F.R.D. 73 (N.D. New York 2003) (collecting cases and authorities).

REQUEST FOR ADMISSION NO. 120:

Following the fungal meningitis outbreak, of the hospitals in the representative sample of acute-care hospitals participating in Medicare that outsourced the compounding of compounded sterile preparations, 83% required compliance with USP 797, 71% reviewed quality reports provided by the outside pharmacy, 27% reviewed quality reports provided by a third party, 22%

conducted onsite visits at the outside pharmacy, and 9% tested the preparations provided by the outsource pharmacy.[64]

RESPONSE TO REQUEST FOR ADMISSION NO. 120:

Plaintiffs object to this RFA as overly broad and unduly burdensome in that it requires Plaintiffs to conduct a survey of a "representative sample of acute-care hospitals participating in Medicare." Plaintiffs further object because there is insufficient information available as to determine whether any survey was conducted with a sufficient sample to be considered a "representative sample" and Plaintiffs are not in possession of sufficient information to admit or deny. Plaintiffs further state that Plaintiffs' Counsel made reasonable inquiry regarding the matters stated in this request, and the information known or readily obtainable by the Plaintiffs' Counsel is insufficient to enable the Plaintiffs' Counsel to admit or deny this request. The information necessary to respond to this RFA is in the possession of third parties, and Plaintiffs have made a reasonable inquiry as to the documents within its possession, and such information is insufficient to admit or deny. Further, Rule 36 does not impose upon Plaintiffs the duty to investigate or obtain documents within the possession of third parties in order to obtain information necessary to respond to an RFA. *See e.g., Henry v. Champlain Enterprises, Inc.*, 212 F.R.D. 73 (N.D. New York 2003) (collecting cases and authorities).

REQUEST FOR ADMISSION NO. 121:

Despite the survey taking place after the 2012 fungal meningitis outbreak, "few hospitals (11 of 236) in [the] sample reported problems with product contamination. . ."[65]

[64] Exhibit E.
[65] Exhibit E.

RESPONSE TO REQUEST FOR ADMISSION NO. 121:

Plaintiffs object to this RFA as overly broad and unduly burdensome in that it requires Plaintiffs to conduct a survey of a "representative sample of acute-care hospitals participating in Medicare." Plaintiffs further object because there is insufficient information available as to determine whether any survey was conducted with a sufficient sample to be considered a "representative sample" and Plaintiffs are not in possession of sufficient information to admit or deny. Plaintiffs further state that Plaintiffs' Counsel made reasonable inquiry regarding the matters stated in this request, and the information known or readily obtainable by the Plaintiffs' Counsel is insufficient to enable the Plaintiffs' Counsel to admit or deny this request. The information necessary to respond to this RFA is in the possession of third parties, and Plaintiffs have made a reasonable inquiry as to the documents within its possession, and such information is insufficient to admit or deny. Further, Rule 36 does not impose upon Plaintiffs the duty to investigate or obtain documents within the possession of third parties in order to obtain information necessary to respond to an RFA. *See e.g.*, *Henry v. Champlain Enterprises, Inc.*, 212 F.R.D. 73 (N.D. New York 2003) (collecting cases and authorities).

Plaintiffs further object to this Request as it is vague in that the term "after the 2012 fungal meningitis outbreak" is ambiguous. Plaintiffs further object to this Request as the term "the survey" is vague.

REQUEST FOR ADMISSION NO. 122:

"Half of all hospitals made changes or planned to make changes to CSP sourcing practices in response to the fall 2012 outbreak[.] Overall, 56% of hospitals made changes to CSP sourcing practices in 2012 or plan to make changes in 2013."[66]

RESPONSE TO REQUEST FOR ADMISSION NO. 122:

Plaintiffs object to this RFA as it is unlimited in time and Plaintiffs cannot admit or deny this RFA based on an unlimited timeframe. Plaintiffs further object to this RFA as overly broad and unduly burdensome in that it requires Plaintiffs to conduct a survey of a "representative sample of acute-care hospitals participating in Medicare." Plaintiffs further object because there is insufficient information available as to determine whether any survey was conducted with a sufficient sample to be considered a "representative sample" and Plaintiffs are not in possession of sufficient information to admit or deny. Plaintiffs further state that Plaintiffs' Counsel made reasonable inquiry regarding the matters stated in this request, and the information known or readily obtainable by the Plaintiffs' Counsel is insufficient to enable the Plaintiffs' Counsel to admit or deny this request. The information necessary to respond to this RFA is in the possession of third parties, and Plaintiffs have made a reasonable inquiry as to the documents within its possession, and such information is insufficient to admit or deny. Further, Rule 36 does not impose upon Plaintiffs the duty to investigate or obtain documents within the possession of third parties in order to obtain information necessary to respond to an RFA. *See e.g.*, *Henry v. Champlain Enterprises, Inc.*, 212 F.R.D. 73 (N.D. New York 2003) (collecting cases and authorities).

[66] Exhibit E.

REQUEST FOR ADMISSION NO. 123:

The American Society of Health System Pharmacists ("ASHP") Research and Education Foundation's "Outsourcing Sterile Products Preparation: Contractor Assessment Tool" was not released until June 29, 2011.

RESPONSE TO REQUEST FOR ADMISSION NO. 123:

Plaintiffs admit that there is a version of a document entitled, "Outsourcing Sterile Products Preparation: Contractor Assessment Tool" that bears a copyright date of 2011. With regard to when this document was released, Plaintiffs state Plaintiffs' Counsel made reasonable inquiry regarding the matters stated in this request, and the information known or readily obtainable by the Plaintiffs' Counsel is insufficient to enable the Plaintiffs' Counsel to admit or deny this request. The information necessary to respond to this RFA is in the possession of third parties, and Plaintiffs have made a reasonable inquiry as to the documents within its possession, and such information is insufficient to admit or deny. Further, Rule 36 does not impose upon Plaintiffs the duty to investigate or obtain documents within the possession of third parties in order to obtain information necessary to respond to an RFA. *See e.g., Henry v. Champlain Enterprises, Inc.*, 212 F.R.D. 73 (N.D. New York 2003) (collecting cases and authorities).

REQUEST FOR ADMISSION NO. 124:

The ASHP Research and Education Foundation developed the "ASHP Guidelines on Outsourcing Sterile Compounding Services" to assist health care organizations in choosing a compounding pharmacy when outsourcing the facility's existing in-house compounding services.

RESPONSE TO REQUEST FOR ADMISSION NO. 124:

Plaintiffs admit that the ASHP Foundation "strongly encourages hospitals/health systems to use this tool along with site visits to ensure a comprehensive review of potential sterile products outsourcing organizations. Items that should be closely evaluated during the site visit are indicated throughout the tool."

As to any other statement contained in RFA 124, Plaintiffs object to this RFA because it requires Plaintiffs to speculate as to why a document was or was not developed. Plaintiffs further state that Plaintiffs' Counsel made reasonable inquiry regarding the matters stated in this request, and the information known or readily obtainable by the Plaintiffs' Counsel is insufficient to enable the Plaintiffs' Counsel to admit or deny this request. The information necessary to respond to this RFA is in the possession of third parties, and Plaintiffs have made a reasonable inquiry as to the documents within its possession, and such information is insufficient to admit or deny. Further, Rule 36 does not impose upon Plaintiffs the duty to investigate or obtain documents within the possession of third parties in order to obtain information necessary to respond to an RFA. *See e.g.*, *Henry v. Champlain Enterprises, Inc.*, 212 F.R.D. 73 (N.D. New York 2003) (collecting cases and authorities).

REQUEST FOR ADMISSION NO. 125:

The ASHP Research and Education Foundation's "Outsourcing Sterile Products Preparation: Contractor Assessment Tool" was developed to assist pharmacy departments in choosing a compounding pharmacy when outsourcing the facility's existing in-house compounding services, but, by its terms, "it does not purport to establish a standard of care."

RESPONSE TO REQUEST FOR ADMISSION NO. 125:

Plaintiffs object to this RFA because it requires Plaintiffs to speculate as to why a document was or was not developed. Plaintiffs further state that Plaintiffs' Counsel made reasonable inquiry regarding the matters stated in this request, and the information known or readily obtainable by the Plaintiffs' Counsel is insufficient to enable the Plaintiffs' Counsel to admit or deny this request. The information necessary to respond to this RFA is in the possession of third parties, and Plaintiffs have made a reasonable inquiry as to the documents within its possession, and such information is insufficient to admit or deny. Further, Rule 36 does not impose upon Plaintiffs the duty to investigate or obtain documents within the possession of third parties in order to obtain information necessary to respond to an RFA. *See e.g., Henry v. Champlain Enterprises, Inc.*, 212 F.R.D. 73 (N.D. New York 2003) (collecting cases and authorities).

Further, to the extent that this RFA is meant to establish the "standard of care" applicable in any claim pending this MDL, Plaintiffs object because any such request would require Plaintiffs to admit to a legal conclusion which is not a permissible use of Rule 36 RFAs. *See e.g., Iantosca v. Benistar Admin Servs., Inc.*, Case No. 08-11785, 2012 U.S. Dist. LEXIS 7896 (D. Mass. 2012); *In re Tobkin*, 578 Fed. Appx. 962 (11th Cir. 2014).

REQUEST FOR ADMISSION NO. 126:

Ameridose, NECC, ARL Bio Pharma, and the FDA were all exhibitors at the 46th ASHP Midyear Clinical Meeting & Exhibition.[67]

[67] http://www.ashp.org/DocLibrary/Midyear11/MCM11YellowPages.aspx.

RESPONSE TO REQUEST FOR ADMISSION NO. 126:

Admit that the reference document shows that the aforementioned entities were scheduled to be exhibitors at the 46th ASHP Midyear clinic Meeting and Exhibition.

REQUEST FOR ADMISSION NO. 127:

ASHP classified Ameridose and NECC as generic pharmaceutical exhibitors at the 46th ASHP Midyear Clinical Meeting & Exhibition.[68]

RESPONSE TO REQUEST FOR ADMISSION NO. 127:

Plaintiffs' Counsel made reasonable inquiry regarding the matters stated in this request, and the information known or readily obtainable by the Plaintiffs' Counsel is insufficient to enable the Plaintiffs' Counsel to admit or deny this request. The information necessary to respond to this RFA is in the possession of third parties, and Plaintiffs have made a reasonable inquiry as to the documents within its possession, and such information is insufficient to admit or deny. Further, Rule 36 does not impose upon Plaintiffs the duty to investigate or obtain documents within the possession of third parties in order to obtain information necessary to respond to an RFA. *See e.g.*, *Henry v. Champlain Enterprises, Inc.*, 212 F.R.D. 73 (N.D. New York 2003) (collecting cases and authorities).

REQUEST FOR ADMISSION NO. 128:

Ameridose, NECC, and the FDA were all exhibitors at the ASHP 2012 Summer Meeting & Exhibition.[69]

[68] http://www.ashp.org/DocLibrary/Midyear11/MCM11YellowPages.aspx.
[69] http://www.ashp.org/DocLibrary/SM2011/Exhibitor-Yellow-Pages.aspx.

RESPONSE TO REQUEST FOR ADMISSION NO. 128:

Admit that the reference document shows that the aforementioned entities were scheduled to be exhibitors at the ASHP 2012 Summer Meeting & Exhibition.

REQUEST FOR ADMISSION NO. 129:

Ameridose, NECC, and the FDA were all exhibitors at the ASHP 2011 Summer Meeting & Exhibition.[70]

RESPONSE TO REQUEST FOR ADMISSION NO. 129:

Admit that the reference document shows that the aforementioned entities were scheduled to be exhibitors at the ASHP 2011 Summer Meeting & Exhibition.

REQUEST FOR ADMISSION NO. 130:

Fungal contamination of MPA purchased from NECC was not reasonably foreseeable to the Defendants.

RESPONSE TO REQUEST FOR ADMISSION NO. 130:

Plaintiffs object to the extent that this RFA requires Plaintiffs to admit to a legal conclusion which is not a permissible use of Rule 36 RFAs. *See e.g.*, *Iantosca v. Benistar Admin Servs., Inc.*, Case No. 08-11785, 2012 U.S. Dist. LEXIS 7896 (D. Mass. 2012); *In re Tobkin*, 578 Fed. Appx. 962 (11th Cir. 2014).

REQUEST FOR ADMISSION NO. 131:

Exhibit F and Exhibit G identify health care providers and facilities that purchased products from NECC as determined by the FDA in carrying out its authorized activities.

[70] http://www.ashp.org/DocLibrary/SM2011/SM11-YellowPages-Web.aspx.

RESPONSE TO REQUEST FOR ADMISSION NO. 131:

Admitted that Exhibits F and G are a list of customers that purchased products from NECC as compiled by either the FDA or NECC. As to the remaining allegations, Plaintiffs object to the extent that this RFA requires Plaintiffs to admit to a legal conclusion which is not a permissible use of Rule 36 RFAs. *See e.g.*, *Iantosca v. Benistar Admin Servs., Inc.*, Case No. 08-11785, 2012 U.S. Dist. LEXIS 7896 (D. Mass. 2012); *In re Tobkin*, 578 Fed. Appx. 962 (11th Cir. 2014).

REQUEST FOR ADMISSION NO. 132:

The health care providers and facilities identified in Exhibit G purchased the products from NECC in the amounts identified in Exhibit G.

RESPONSE TO REQUEST FOR ADMISSION NO. 132:

Admitted that Exhibit G identifies customers that purchased products from NECC as compiled by either the FDA or NECC.

REQUEST FOR ADMISSION NO. 133:

Exhibit H identifies health care providers and facilities that purchased MPA from NECC and received product from lots #05212012@68, #06292012@26, and #08102012@51 compounded by NECC.

RESPONSE TO REQUEST FOR ADMISSION NO. 133:

Admitted that Exhibit H identifies customers that purchased products from NECC as compiled by the CDC.

REQUEST FOR ADMISSION NO. 134:

Exhibits F, G, and H are records and data compilations of public agencies as contemplated by Fed. R. Evid. 803(8).

RESPONSE TO REQUEST FOR ADMISSION NO. 134:

Plaintiffs' Counsel made reasonable inquiry regarding the matters stated in this request, and the information known or readily obtainable by the Plaintiffs' Counsel is insufficient to enable the Plaintiffs' Counsel to admit or deny this request. The information necessary to respond to this RFA is in the possession of third parties, and Plaintiffs have made a reasonable inquiry as to the documents within its possession, and such information is insufficient to admit or deny. Further, Rule 36 does not impose upon Plaintiffs the duty to investigate or obtain documents within the possession of third parties in order to obtain information necessary to respond to an RFA. *See e.g.*, *Henry v. Champlain Enterprises, Inc.*, 212 F.R.D. 73 (N.D. New York 2003) (collecting cases and authorities).

REQUEST FOR ADMISSION NO. 135:

The Plaintiffs' Steering Committee and/or individual Plaintiffs or counsel for individual Plaintiffs used or relied upon Exhibit F and/or Exhibit G to identify or allege that specific health care providers purchased medication from NECC.

RESPONSE TO REQUEST FOR ADMISSION NO. 135:

Plaintiffs object to this RFA to the extent that it seeks information not reasonably calculated to lead to the discovery of admissible evidence, is overly broad, unduly burdensome, and vague. Plaintiffs further object to the extent that this RFA seeks information that is covered by any applicable privilege.

REQUEST FOR ADMISSION NO. 136:

The Plaintiffs' Steering Committee and/or the individual Plaintiffs or counsel for the individual Plaintiffs used or relied upon Exhibit H to identify or allege that specific health care providers purchased medication from NECC.

RESPONSE TO REQUEST FOR ADMISSION NO. 136:

Plaintiffs object to this RFA to the extent that it seeks information not reasonably calculated to lead to the discovery of admissible evidence, is overly broad, unduly burdensome, and vague. Plaintiffs further object to the extent that this RFA seeks information that is covered by any applicable privilege.

REQUEST FOR ADMISSION NO. 137:

Between May 21, 2012, and October 6, 2012, more than 50 health care facilities/providers in Tennessee purchased medication from NECC.

RESPONSE TO REQUEST FOR ADMISSION NO. 137:

Plaintiffs object to this RFA as overly broad and unduly burdensome in that it requires Plaintiffs' Counsel to conduct a survey of facilities/providers in Tennessee that purchased any medication from NECC. Subject to and without waiving this objection, after making a reasonable investigation, Plaintiffs are without sufficient information to admit or deny this request.

REQUEST FOR ADMISSION NO. 138:

Between May 21, 2012, and October 6, 2012, more than 180 health care facilities/providers in the United States purchased MPA from NECC.[71]

RESPONSE TO REQUEST FOR ADMISSION NO. 138:

Plaintiffs object to this RFA as overly broad and unduly burdensome in that it requires Plaintiffs' Counsel to conduct a survey of facilities/providers in the entire country that purchased any MPA from NECC. Subject to and without waiving this objection, Plaintiffs' Counsel made reasonable inquiry regarding the matters stated in this request, and the information known or readily obtainable by the Plaintiffs' Counsel is insufficient to enable the Plaintiffs' Counsel to admit or deny this request. The information necessary to respond to this RFA is in the possession of third parties, and Plaintiffs have made a reasonable inquiry as to the documents within its possession, and such information is insufficient to admit or deny. Further, Rule 36 does not impose upon Plaintiffs the duty to investigate or obtain documents within the possession of third parties in order to obtain information necessary to respond to an RFA. *See e.g., Henry v. Champlain Enterprises, Inc.*, 212 F.R.D. 73 (N.D. New York 2003) (collecting cases and authorities).

REQUEST FOR ADMISSION NO. 139:

Between May 21, 2012, and October 6, 2012, more than 90 health care facilities/providers in the United States purchased *preservative-free* MPA from NECC.[72]

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[71] Attached as Exhibit I is a summary of the information from Exhibit G, showing only the health care providers/facilities that purchased methylprednisolone acetate from NECC.

[72] Attached as Exhibit J is a summary of the information from Exhibit G, showing only the health care providers/facilities that purchased preservative-free methylprednisolone acetate from NECC.

RESPONSE TO REQUEST FOR ADMISSION NO. 139:

Plaintiffs object to this RFA as overly broad and unduly burdensome in that it requires Plaintiffs' Counsel to conduct a survey of facilities/providers in the entire country that purchased any preservative free MPA from NECC. Subject to and without waiving this objection, Plaintiffs' Counsel made reasonable inquiry regarding the matters stated in this request, and the information known or readily obtainable by the Plaintiffs' Counsel is insufficient to enable the Plaintiffs' Counsel to admit or deny this request. The information necessary to respond to this RFA is in the possession of third parties, and Plaintiffs have made a reasonable inquiry as to the documents within its possession, and such information is insufficient to admit or deny. Further, Rule 36 does not impose upon Plaintiffs the duty to investigate or obtain documents within the possession of third parties in order to obtain information necessary to respond to an RFA. *See e.g., Henry v. Champlain Enterprises, Inc.*, 212 F.R.D. 73 (N.D. New York 2003) (collecting cases and authorities).

REQUEST FOR ADMISSION NO. 140:

Between May 21, 2012, and October 6, 2012, more than 3,000 health care facilities/providers in the United States purchased medication from NECC.

RESPONSE TO REQUEST FOR ADMISSION NO. 140:

Plaintiffs object to this RFA as overly broad and unduly burdensome in that it requires Plaintiffs' Counsel to conduct a survey of facilities/providers in the entire country that purchased any MPA from NECC. Subject to and without waiving this objection, Plaintiffs' Counsel made reasonable inquiry regarding the matters stated in this request, and the information known or readily obtainable by the Plaintiffs' Counsel is insufficient to enable the Plaintiffs' Counsel to

admit or deny this request. The information necessary to respond to this RFA is in the possession of third parties, and Plaintiffs have made a reasonable inquiry as to the documents within its possession, and such information is insufficient to admit or deny. Further, Rule 36 does not impose upon Plaintiffs the duty to investigate or obtain documents within the possession of third parties in order to obtain information necessary to respond to an RFA. *See e.g., Henry v. Champlain Enterprises, Inc.*, 212 F.R.D. 73 (N.D. New York 2003) (collecting cases and authorities).

REQUEST FOR ADMISSION NO. 141:

Brigham and Women's Hospital performed an on-site audit of NECC in May 2012.

RESPONSE TO REQUEST FOR ADMISSION NO. 141:

Admit that an agent of Brigham and Women's Hospital visited NECC in May of 2012. Denied as to all other allegations in this RFA.

REQUEST FOR ADMISSION NO. 142:

Brigham and Women's Hospital continued purchasing from NECC after performing the on-site audit, and purchased product until at least September 18, 2012.[73]

RESPONSE TO REQUEST FOR ADMISSION NO. 142:

Admit that Exhibits F and G show that Brigham and Women's Hospital purchased products from NECC after May of 2012. Denied as to all other allegations in this RFA.

[73] *See* Exhibits F and G.

Dated: December 23, 2014

Respectfully submitted,

/s/ J. Gerard Stranch, IV

J. Gerard Stranch, IV
Benjamin A. Gastel
BRANSETTER, STRANCH & JENNINGS PLLC
227 Second Avenue North
Nashville, TN 37201
Telephone: (615) 254-8801
Facsimile: (615) 255-5419
gerards@branstetterlaw.com
beng@branstetterlaw.com

Plaintiffs' Counsel

CERTIFICATE OF SERVICE

I, J. Gerard Stranch, IV, hereby certify that I delivered a copy of the foregoing document via U.S. Mail and email to the attorneys listed on the attached sheet.

Dated: December 23, 2014

/s/ J. Gerard Stranch, IV
J. Gerard Stranch, IV

LIST OF DEFENDANTS AND COUNSEL

DEFENDANT	COUNSEL
BKC Pain Specialists Nikesh Batra Adil Katabay Gururau Sudarshan Advanced Pain & Anethesia Consultants PC d/b/a APAC Centers for Pain Management Randolph Y. Chang, MD Cincinnati Pain Management Consultants, Inc. Cincinnati Pain Management Consultants, Ltd.	Anthony E. Abeln (aabeln@morrisonmahoney.com) Tory A. Weigand (tweigand@morrisonmahoney.com) Morrison Mahoney, LLP 250 Summer Street Boston, MA 02210 (617) 737-8885
Thorek Memorial Hospital	Kip J. Adams (kip.adams@lewisbrisbois.com) Lewis Brisbois Bisgaard & Smith, LLP One International Place, 3rd Floor Boston, MA 02110 (857) 313-3950 Scott C. Bentivenga Lewis Brisbois Bisgaard & Smith, LLP 550 West Adams Street, Suite 300 Chicago, IL 60661 (312) 345-1718 Thomas J. Schlesinger (tschlesinger@lbbslaw.com) Lewis Brisbois Bisgaard & Smith, LLP 77 Water Street, Suite 2100 New York, NY 10005 (212) 232-1354
Hartford County Ambulatory Surgery Center, LLC	Thomas J. Althauser (althauser@ewmd.com) Eccleston & Wolf, PC 7240 Parkway Drive, 4th Floor Hanover, MD 21076-1378 (410) 752-7474
North Carolina Orthopaedic Clinic	Mark E. Anderson (manderson@mcguirewoods.com) McGuire Woods LLP 434 Fayetteville St., Suite 2600 P.O. Box 27507 Raleigh, NC 27611

	(919) 755-6678
Surgery Center of Wilson, LLC	David H. Batten (dbatten@battenlee.com) C. Houston Foppiano (hfoppiano@battenlee.com) G. Adam Moyers (amoyers@battenlee.com) Batten Lee, PLLC 4141 Parklake Avenue, Suite 350 Raleigh, NC 27612 (919) 439-2221
Howell Allen Clinic, A Professional Corporation St. Thomas Outpatient Neurosurgical Center, LLC Specialty Surgery Center, PLLC Debra Schamberg Dr. Donald Jones John Culclasure Kenneth R. Lister Kenneth Lister, M.D., P.C. Neurosurgical Group of Chattanooga	Alan S. Bean (alan@gideoncooper.com) C.J. Gideon (cj@gideoncooper.com) Matthew H. Cline (matt@gideoncooper.com) Chris Tardio (chris@gideoncooper.com) Gideon Cooper & Essary, PLLC 315 Deaderick Street, Suite 1100 Nashville, TN 37238 (615) 254-0400
DBMJ Rehabilitation Services, PLLC, d/b/a Neuromuscular and Rehabilitation Associates of Northern Michigan Dr. Stephen Andriese	Brett J. Bean Timothy J. Dardas (tdardas@hghblaw.com) Hackney, Grover, Hoover & Bean 1715 Abbey Road, Suite A East Lansing, MI 48823 (517) 333-0306
Erlanger Health System	John B. Bennett Arthur P. Brock Cara E. Weiner Spears, Moore, Rebman & Williams, PC 801 Broad Street, 6th Floor Chattanooga, TN 37402 (423) 756-7000
Premier Orthopaedic & Sports Medicine Associates of Southern New Jersey, LLC Premier Orthopaedic Associates Surgical	Jay J. Blumberg (jjblumberg@blumberglawoffices.com) Christopher M. Wolk Law Offices of Jay Blumberg

Center, LLC Kimberly Yvette Smith, MD Dr. Vanette Perkins	158 Delaware Street P.O. Box 68 Woodbury, NJ 08096 (856) 848-7472
Marion Pain Management Center, Inc.	Robert L. Boston (rboston@campbell-trial-lawyers.com) David M. Rogers (drogers@campbell-trial-lawyers.com) Campbell Campbell Edwards & Conroy, PC One Constitution Plaza Boston, MA 02129 (617) 241-3011
Rochester Brain & Spine Neurosurgery & Pain Management, LLC	Alan J. Bozer (abozer@phillipslytle.com) Joanna J. Chen (jchen@phillipslytle.com) Phillips Lytle, LLP One Canalside 125 Main Street Buffalo, NY 14203 (716) 847-8400 Michael E. Hager (mehager175@hotmail.com) 11 Beacon Street, Suite 1200 Boston, MA 02108 (617) 723-7133
Unifirst Corporation a/d/b/a Uniclean Cleanroom Services	Roberto M. Braceras (rbraceras@goodwinprocter.com) Abigail K. Hemani (ahemani@goodwinprocter.com) Joshua L. Launer (jlauner@goodwinprocter.com) Michael K. Murray (mmurray@goodwinprocter.com) James Rehnquist (jrehnquist@goodwinprocter.com) Damian W. Wilmot (dwilmot@goodwinprocter.com) Goodwin Procter, LLP Exchange Place 53 State Street Boston, MA 02109

	(617) 570-1895
Martin Kelvas St. Thomas Health St. Thomas Network St. Thomas West Hospital Ascension Health Ascension Health Alliance St. Thomas Hospital West f/k/a St. Thomas Hospital	Stephen J. Brake (sbrake@nutter.com) Sarah P. Kelly (skelly@nutter.com) Nutter, McClennen & Fish, LLP Seaport West 155 Seaport Boulevard Boston, MA 02210-2604 (617) 439-2223 Marcy H. Greer (mgreer@adjtlaw.com) Alexander Dubose Jefferson & Townsent 515 Congress Avenue, Suite 2350 Austin, TX 78701 (512) 716-8310 Eric J. Hoffman (eric.hoffman@nortonrosefulbright.com) Yvonne. K. Puig (yvonne.puig@nortonrosefulbright.com) Adam T. Schramek (adam.schramek@nortonrosefulbright.com) Fulbright & Jaworski, LLP 98 San Jacinto Boulevard, Suite 1100 Austin, TX 78701 (512) 536-2450
Hahnemann University Hospital Tenet HealthSystem Hahnemann, LLC	Barbara Hayes Buell (barbara.buell@smithduggan.com) Smith Duggan Buell & Rufo, LLP Lincoln North 55 Old Bedford Road Lincoln, MA 01773 (617) 228-4460

Insight Health Corp. Insight Imaging, Inc.	Stephen D. Busch (sbusch@mcguirewoods.com) Samuel T. Towell (stowell@mcguirewoods.com) Christopher E. Trible (ctrible@mcguirewoods.com) McGuire Woods, LLP One James Center 901 E. Cary Street Richmond, VA 2319-4030 (804) 775-4378 Diane Flannery (dflannery@mcguirewoods.com) McGuire Woods, LLP One James Center 901 E. Cary Street Richmond, VA 23219 (804) 774-1000 Albert L. Hogan, III (al.hogan@skadden.com) Ron E. Meisler (ron.meisler@skadden.com) Skadden, Arps, Slate, Meagher & Flom, LLP 155 N. Wacker Drive Chicago, IL 60606 (312) 407-0700 Matthew J. Matule (matthew.matule@skadden.com) Skadden, Arps, Slate, Meagher & Flom, LLP 500 Boylston Street Boston, MA 02116 (617) 573-4887
Ocean State Pain Management, Inc. (RI)	Sean E. Capplis (scapplis@capplisandconnors.com) Ficksman & Conley, LLP 98 N. Washington Street, Suite 500 Boston, MA 02114 (617) 720-1515 Matthew R. Connors (mconnors@capplisandconnors.com)

	Connors & Carrol, PC 18 Tremont Street, Suite 220 Boston, MA 02108
Medical Advanced Pain Specialists, PA David M. Schultz, MD	Clare F. Carroll (cfc@mbblaw.com) Robert L. Bouley (rlb@mbblaw.com) McCarthy, Bouley & Barry, PC 47 Thorndike Street Cambridge, MA 02141 (617) 225-2211
Dr. O'Connell's Pain Care Center Dr. O'Connell's Pain Care Center, Inc.	William E. Christie (wchristie@shaheengordon.com) Benjamin T. Siracusa Hillman (bsiracusahillman@shaheengordon.com) Shaheen & Gordon, PA 107 Storrs Street P.O. Box 2703 Concord, NH 03302-2703 (603) 225-7262
Alaunus Pharmaceutical, LLC	Ryan A. Ciporkin (rciporkin@lawson-weitzen.com) Franklin H. Levy (fhlevy@gmail.com) Lawson & Weitzen 88 Black Falcon Avenue, Suite 345 Boston, MA 02210 (617) 439-4990
Ameridose, LLC	Thomas W. Coffey (thomas.coffey@tuckerellis.com) Richard A. Dean (richard.dean@tuckerellis.com) Matthew P. Moriarty (matthew.moriarty@tuckerellis.com) Tucker Ellis, LLP 950 Main Avenue, Suite 1100 Cleveland, OH 44113 (216) 592-5000 Scott H. Kremer (kremer@tsd-lawfirm.com) Tucker, Heifetz & Saltzman

	Three School Street Boston, MA 02108 (617) 557-9696 Matthew E. Mantalos (mantalos@tsd-lawfirm.com) Paul Saltzman (Saltzman@tds-lawfirm.com) Scott J. Tucker (tucker@tsd-lawfirm.com) Tucker, Saltzman & Dyer, LLP 50 Congress Street Boston, MA 02109 (614) 986-4222
Universal Pain Management Medical Corporation	Paul M. Corson (pcorson@lawbrandmeyer.com) Law Brandmeyer Packer, LLP 245 S. Los Robles Avenue, Suite 600 Pasadena, CA 91101 (626) 243-5500
Interventional Spine & Sports Medicine, PC	Matthew C. Daly (mdaly@golenbock.com) Martin S. Hyman (mhyman@golenbock.com) Golenbock Eiseman Assor Bell & Peskoe, LLP 437 Madison Avenue New York, NY 10022 (212) 907-7300
Mercy Health System of SE Pennsylvania Nasareth Hospital	Daniel J. Divis (ddivis@gmdlfirm.com) Frank A. Gerolamo Gerolamo, McNulty, Divis & Lewbart 121 South Broad Street, Suite 1400 Philadelphia, PA 19107 (215) 790-8400
Orlando Center for Outpatient Surgery, LP	Theresa A. Domenico (tdomenico@mccumberdaniels.com) McCumber, Daniels, Buntz, Hartig & Puig, PA 204 S. Hoover Boulevard, Suite 130 Tampa, FL 33609 (813) 287-2822

Liberty Industries, Inc.	Nicole D. Dorman (ndorman@nicoledormanlaw.com Law office of Nichole D. Dorman, LLC P.O. Box 1142 Glastonbury, CT 06033 (860) 463-6873 Peter G. Hermes (phermes@hermesnetburn.com) Scott S. Spearing (sspearing@hermesnetburn.com) Hermes, Netburn, O'Connor & Spearing 265 Franklin Street, 7th Floor Boston, MA 02110 (617) 728-0050 Kara A. Loridas (kara.loridas@gmail.com Balber, Pickard, Battistoni, Maldonado & VanDerTuin, PC 1370 Avenue of the Americas New York, NY 10019-4602 (617) 571-6473 Dianne E. Ricardo (Dianne.ricardo@mclane.com) McLane, Graf, Raulerson & Middleton 900 Elm Street P.O. Box 326 Manchester, NH 03105-0326 (603) 628-1280
OSMC	Robert James Durant (rdurant@eapdlaw.com) Edwards Angell Palmer & Dodge, LLP 2800 Financial Plaza Providence, RI 02903 (401) 528-5855
The South Bend Clinic, LLP	David E. Fialkow (david.fialkow@nelsonmullins.com) Nelson Mullins One Post Office Square, 30th Floor Boston, MA 02109 (617) 573-4703

Carlos Jassir, M.D., Pain Management Center of West Orange	Richard H. Ford (rford@wickersmith.com) Wicker, Smith, O'Hara, McCoy & Ford, PA P.O. Box 2753 Orlando, FL 32802 (407) 843-3939
Dallas Back Pain Management/Momentum Pain Management Abbeselom Ghermay	Elizabeth Masters Fraley (efraley@fraley-law.com) Fraley & Fraley, LLP 901 Main Street, Suite 6300 Dallas, TX 75202 (214) 761-6460
Carilion Surgery Center New River Valley, LLC, d/b/a New River Valley Surgery Center, LLC	Michael Preston Gardner (micheal.gardner@leclairryan.com) Leclair Ryan, A Professional Corporation 18th Floor, Wells Fargo Tower 10 South Jefferson Street Roanoke, VA 24011 (540) 510-3000
HCA Health Services of Tennessee, Inc. Surgical Park Center, Ltd. Sahara Outpatient Surgery Center, Ltd. Sunrise Hospital & Medical Center, LLC Wilson Chu	Mark P. Goodman (mpgoodman@debevoise.com) Maura K. Monaghan (mkmonagh@debevoise.com) Cari A. Wint (cawint@debevoise.com) Debevoise & Plimpton, LLP 919 Third Avenue New York, NY 10022 (212) 909-6000
South Jersey Healthcare South Jersey Regional Medical Center	Stephen A. Grossman (sgrossman@mmwr.com) Louis R. Moffa, Jr. (lmoffa@mmwr.com) Kristin Muir Mykulak (kmykulak@mmwr.com) Montgomery McCracken Walker & Rhoads, LLP 457 Haddonfield Road, Suite 600 Cherry Hill, NJ 08003 (856) 488-7700 Michael B. Hayes

	(mhayes@mmwr.com) Montgomery, McCracken, Walker & Rhoads, LLP 123 South Broad Street Philadelphia, PA 19109 (215) 772-7211
Michigan Pain Specialists, PLLC	Randy J. Hackney C. Mark Hoover Hackney Grover Hoover & Bean 1715 Abbey Road, Suite A East Lansing, MI 48823 (517) 333-0306 David M. Thomas (dthomas@rmrtt.com) Rutledge, Manion, Rabaut, Terry & Thomas, PC Fort Washington Plaza, Suite 1600 333 West Fort Street Detroit, MI 48226 (313) 961-9344
Surgery Center Associates of High Point, LLC High Point Surgery Center	Carrie A. Hanger (carrie.hanger@smithmoorelaw.com) Terrill J. Harris (terri.harris@smithmoorelaw.com) Smith, Moore, Leatherwood, LLP 300 N. Greene Street, Suite 1400 P.O. Box 21927 Greensboro, NC 27420 (336) 378-5200
Glaser Pain Institute Jeffrey B. Glaser	Stephanie R. Hanning (shanning@schmidvoiles.com) Schmid & Voiles 333 South Hope Street, 8th Floor Los Angeles, CA 90071 (213) 473-8700
The Rothman Institute The Rothman Institute at Nazareth Hospital William M. Anderson, MD	Brook Hastings (bhasting@obrlaw.com) O'Brien & Ryan 2250 Hickory Road, Suite 300 Plymouth Meeting, PA 19462 (610) 834-6272

Medical Sales Management, Inc.	Brady J. Hermann (bjh@michaelsward.com) Daniel M. Rabinovitz (dmr@michaelsward.com) Nicki Samson (ns@michaelsward.com) Michaels, Ward & Rabinovitz One Beacon Street, 2nd Floor Boston, MA 02108 (617) 350-4040
Pain Associates of Charleston, LLC d/b/a Invervene MD	Robert Homes Hood, Jr. (bobbyjr.hood@hoodlaw.com) Hood Law Firm 172 Meeting Street Charleston, SC 29401 (843) 577-4435
Southeast Michigan Surgical Hospital	Kathryn J. Humphrey (khumphrey@dykema.com) 400 Renaissance Center Detroit, MI 48243-1668 (313) 568-6848 Steven Weiss (sweiss@ssfpc.com) Schatz, Schwartz & Fentin, PC 1440 Main Street Springfield, MA 01103 (413) 737-1131
Image Guided Pain Management, PC Dr. John Mathis Robert O'Brien	John Thomas Jessee (john.jessee@leclairryan.com) Nancy Fuller Reynolds (Nancy.reynolds@leclairryan.com) LeClair Ryan, A Professional Corporation 1800 Wachovia Tower, Drawer 1200 Roanoke, VA 24006 (540) 510-3018
Box Hill Surgery Center, LLC Pain Medicine Specialists, PA Surgicenter of Bel Air, LLC	Gregory K. Kirby (gkirby@pklaw.com) Pessin Katz Law, PA 901 Dulaney Valley Road, Suite 400 Towson, MD 21204

	(410) 938-8800
Nitesh Bhagat	Joseph R. Lang (jlang@lenoxlaw.com) Lenox, Socey, Formidoni, Giordano, Cooley, Lang & Casey, LLC 3131 Princeton Pike, Building 1B, Suite 104 Lawrenceville, NJ 08648 (609) 896-2000 John M. Lovely (jlovely@cashmanlovely.com) Cahsman & Lovely 60 Austin Street, Suite 210 Newtonville, MA 02460 (617) 964-7870
ARL Bio Pharma, Inc.	Courtney Ann Longo (clongo@donovanhatem.com) Kristen R. Ragosta (kragosta@donovanhatem.com) Pamela C. Selvarajah (pselvarajah@donovanhatem.com) Kenneth B. Walton (kwalton@donovanhatem.com) Donovan Hatem, LLP 53 State Street, 8th Floor Boston, MA 02109 (617) 406-4523
Baltimore Pain Management Center	Michelle J. Marzullo (mmarzullo@moodklaw.com) Marks, O'Neill, O'Brien, Doherty & Kelly, PC 600 Baltimore Avenue, Suite 305 Towson, MD 21204 (410) 339-6880
Allegheny Pain Management, PC	Allen P. Neely (apneely@mqblaw.com) McQuaide Blasko, Inc. 811 University Drive State College, PA 16801 (814) 238-4926
Encino Outpatient Surgery Center	Cynthia A. Palin (cpalin@prindlelaw.com)

	Prindle, Amaro, Goetz, Hillyard, Barnes & Reinholtz 310 Golden Shore, 4th Floor Long Beach, CA 90802 (562) 436-3946
Doylestown Hospital	John B. Reiss Doylestown Hospital 595 West State Street Doylestown, PA 18901 (215) 345-2212
Victory Mechanical Services, Inc. Victory Heating & Air Conditioning Co., Inc.	Michael P. Sams (mpsams@kandslegal.com) Kenney & Sams, PC 225 Turnpike Road Southborough, MA 01772 (508) 490-8500
Greenspring Surgical Center	John T. Sly Waranch & Brown, LLC 1301 York Road, Suite 300 Lutherville, MD 21093 (410) 821-3511
Pain Consultants of West Florida	Halley M. Stephens (hstephens@fmhslaw.com) Fuller, Mitchell, Hood & Stephens, LLC 2565 Barrington Circle Tallahassee, FL 32308 (850) 222-0770
High Point Regional Health f/k/a High Point Regional Health System, d/b/a High Point Regional Hospital	Joan O. Vorster (jovorster@mirickoconnell.com) Courtney D. Cruz (ccruz@mirickoconnell.com) Mirick O'Connell Demallie & Lougee 100 Front Street Worcester, MA 01608 (508) 791-8500
Sequoia Orthopaedic & Spine Institute, Inc. Frank Feng, D.O.	Lawrence E. Wayne , NCAED McCormick Barstow LLP 7647 North Fresno Street Fresno, CA 93720 (559) 433-1300

Sequoia Surgery Center Holdings, Inc.	William M. White (wwhite@bakermanock.com) Baker, Mancok & Jensen Fig Garden Financial Center 5260 N. Palm Avenue 4th Floor Fresno, CA 93704 (559) 432-5400 ext. 241